



IAF Informative Document

IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications

Issue 1

(IAF ID 13:2017)

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF Accreditation Body Members are accepted globally.

Accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation schemes. The structure and scope of the IAF MLA is detailed in IAF PR 4 - Structure of IAF MLA and Endorsed Normative Documents.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.
- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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INTRODUCTION TO IAF INFORMATIVE DOCUMENTS

This IAF Informative Document reflects the consensus of IAF members on this subject and is intended to support the consistent application of requirements. However, being a document for information purposes only, IAF Accreditation Body Members, and the Conformity Assessment Bodies they accredit, are not under any obligation to use or comply with anything in this document.

IAF Medical Device Nomenclature (IAF MDN) Including Medical Devices Risk Classifications

1. INTRODUCTION

This IAF Medical Device Nomenclature document (IAF MDN) is an informative document that was developed for the support of IAF MD8 and MD9. It provides long established medical device names and classifications, where risk classifications do not exist in the Global Medical Device Nomenclature (GMDN).

Within this guide, there are more than 6,000 specific medical device names, divided into 16 categories. The IAF MDN is useful to Accreditation Bodies (ABs) and Conformity Assessment Bodies (CABs), as well as those preparing for an audit or accreditation assessment.

IAF MDN includes multiple risk classifications to help provide a general view of the level of risk of a device. The IAF MDN is clearly an informative document, and is not to be used for determining risk classification for regulatory purposes.

Manufacturer's Obligations to a Quality Management System				
Medical Device Risk Classification	GHTF Risk Class	IAF accredited certification to ISO 13485 Not Required	IAF accredited certification to ISO 13485 Required	IAF accredited certification to ISO 13485 Including Design and Development Controls
High Risk	D			x
Medium-high Risk	C			x
Medium-low Risk	B		x	
Low Risk	A	x*		

*Low risk medical devices are exempt from ISO 13485 Certification

Illustration from the IAF Initiative for Accredited Certification to ISO 13485 – Medical Devices

2. SCOPE

The scope of the document in relation to: (1) its relationship to ISO 13485 and conformity assessment requirements, (2) IAF MDN content- product names, risk

classification assignments, implant, life-sustaining/supporting devices and regulatory use is outlined below.

2.1 Relationship to ISO 13485 and Conformity Assessment Requirements

ISO 13485:2016 is more focused on minimizing medical device risks than any of its preceding revisions. The IAF MDN provides a naming convention and various risk classifications for sharing, communicating, and exchanging information related to most medical devices in circulation worldwide.

The relationships of Risk Class to Conformity Assessment requirements relating to ISO 13485 are set forth in some of the medical device regulations included by reference in the following pages. Unclassified devices are indicated with the letter "U". Above is an illustration that shows a common approach to using ISO 13485, including requirements for Design and Development Controls for higher risk medical devices, and exemptions for lower risk medical devices.

2.2 IAF MDN Content

2.2.1 Product Names

The IAF MDN uses names derived from US FDA Product Codes. These medical device names have been established through decades of use worldwide and were compiled here for their clearest association with a risk classification and their ability to provide a more suitable instrument for further self-study of medical devices and their specific risks.

2.2.2 Risk Classification Assignments

The risk classifications were assigned according to risk rules used in the Global Harmonization Task Force document GHTF/SG1/N77:2012, risk rules indicated in Canadian Regulation SOR98-282 Schedule 1, and the European Medical Device Directive 93/42/EEC Annex IX. All risk classifications from the US FDA were derived from association with medical device "Classification Names" under Part 800 of the US Code of Federal Regulation.

2.2.3 Implant, Life Sustaining/Supporting Devices

Devices that are implanted in the body long term, or devices considered to be Life Sustaining or Life Supporting, are indicated as Y (Yes) and N (No) where known to be related to the device name. These additional identifiers enhance understanding of the area or level of concern related to each device. Implanted, Life Sustaining/Supporting devices often require more risk management within the Quality Management Systems required by ISO 13485.

2.3 Disclaimer – Do not Use This Document for Regulatory Purposes

The IAF MDN is a tool for research and must not be used to meet regulatory purposes as a stand-alone source of information. This document is not to be used by itself to ascertain the risk classification of any medical device for regulatory purposes.

For further information on risk classification, it is recommended that users consider the most current medical device regulations affecting risk classification, and the Final Guidance Document GHTF/SG1/N77:2012 - Principles of Medical Devices Classification.

Risk classifications may vary between regions and economies. It is imperative that each medical device manufacturer use the current medical device regulations adopted within the jurisdictions into which they sell their product, to assure confidence in meeting the regulatory obligations for the markets where they operate.

3. REFERENCES

Canadian Medical Device Regulation SOR 98-282 (Schedule 1)

European Medical Device Directive 93/42/EEC (Annex IX)

GHTF Guidance document SG1-N77

US FDA database

4. MEDICAL DEVICE NOMENCLATURE - INDICATORS OF RISK CLASSIFICATION LEVEL

Risk classification levels are indicated in the IAF MDN with regard to Canadian, European, GHTF Guidance, and US FDA rules are as follows:

	Canada	Europe	GHTF	USA
Low Risk	1	1	A	1
Medium Low Risk	2	2a	B	2
Medium High Risk	3	2b	C	
High Risk	4	3	D	3

End of IAF Informative Document - IAF Medical Device Nomenclature (IAF MDN)
Including Medical Device Risk Classifications.

ANNEX A - MEDICAL DEVICE NOMENCLATURE CHART

Medical Device Categories Reference Index*

Medical Device Category	IAF MDN Reference	Pages
Clinical chemistry and clinical toxicology devices	862	10 - 46
Hematology and pathology devices	864	47 - 69
Immunology and microbiology devices	866	70 - 113
Anesthesiology devices	868	114 - 123
Cardiovascular devices	870	124 - 139
Dental devices	872	140 - 154
Ear, nose, and throat devices	874	155 - 164
Gastroenterology-urology devices	876	165 - 186
General and plastic surgery devices	878	187 - 207
General hospital and personal use devices	880	208 - 219
Neurological devices	882	220 - 229
Obstetrical and gynecological devices	884	230 - 240
Ophthalmic devices	886	241 - 253
Orthopedic devices	888	254 - 269
Physical medicine devices	890	270 - 278
Radiology devices	892	279 - 286

*IAF MDN References link to source material

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62001	1-Nitroso-2-Naphthol (Fluorometric), Free Tyrosine	B	2a	2	1	N	N
62002	2,4-Dinitrofluorobenzene (Spectroscopic), Nitrogen (Amino-Nitrogen)	B	2a	2	1	N	N
62003	2,4-Dinitrophenylhydrazine, Lactate Dehydrogenase	B	2a	2	2	N	N
62004	5-Amp-Phosphate Release (Colorimetric Test), 5'-Nucleotidase	B	2a	2	1	N	N
62005	5-Fluorouracil Assay	B	2a	2	U	N	N
62006	Acetylcholine Chloride, Specific Reagent For Pseudo Cholinesterase	B	2a	2	1	N	N
62007	Acid Phosphatase (Prostatic), Tartrate Inhibited	B	2a	2	2	N	N
62008	Acid Phosphatase, Beta Glycerophosphate	B	2a	2	2	N	N
62009	Acid Phosphatase, Disodium Phenylphosphate	B	2a	2	2	N	N
62010	Acid Phosphatase, Naphthyl Phosphate	B	2a	2	2	N	N
62011	Acid Phosphatase, Nitrophenylphosphate	B	2a	2	2	N	N
62012	Acid Phosphatase, Thymol Blue Monophosphate	B	2a	2	2	N	N
62013	Acid Phosphatase, Thymolphthale Inmonophosphate	B	2a	2	2	N	N
62014	Acid, Alpha-Ketobutyric And Nadh (U.V.), Hydroxybutyric Dehydrogenase	B	2a	2	1	N	N
62015	Acid, Ascorbic, 2,4-Dinitrophenylhydrazine (Spectrophotometric)	B	2a	2	1	N	N
62016	Acid, Delta-Aminolevulinic, Ion-Exchange Columns With Colorimetry	B	2a	2	1	N	N
62017	Acid, Ferric Ion-Sulfuric, Cholesterol	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62018	Acid, Folic, Radioimmunoassay	B	2a	2	2	N	N
62019	Acid, Hydroxyazobenzene-Benzoic, Albumin	B	2a	2	2	N	N
62020	Acid, Lactic, Enzymatic Method	B	2a	2	1	N	N
62021	Acid, Nitrous And Nitrosonaphthol, 5-Hydroxyindole Acetic Acid/Serotonin	B	2a	2	1	N	N
62022	Acid, Oxalacetic And Nadh Oxidation (U.V.), Malic Dehydrogenase	B	2a	2	1	N	N
62023	Acid, Phosphoric-Tungstic (Spectrophotometric), Chloride	B	2a	2	2	N	N
62024	Acid, Pyruvic, Enzymatic (U.V.)	B	2a	2	1	N	N
62025	Acid, Trifluoroacetic, Vitamin A, Hexane Extraction	B	2a	2	1	N	N
62026	Acid, Uric, Acid Reduction Of Ferric Ion	B	2a	2	1	N	N
62027	Acid, Uric, Phosphotungstate Reduction	B	2a	2	1	N	N
62028	Acid, Uric, Uricase (Colorimetric)	B	2a	2	1	N	N
62029	Acid, Uric, Uricase (Gasometric)	B	2a	2	1	N	N
62030	Acid, Uric, Uricase (Oxygen Rate)	B	2a	2	1	N	N
62031	Acid, Uric, Uricase (U.V.)	D	3	2	1	N	N
62032	Acid, Vanilmandelic, Diazo, P-Nitroaniline/Vanillin	B	2a	2	1	N	N
62033	Acid, Vanilmandelic, Electrophoretic Separation	B	2a	2	1	N	N
62034	Adsorbents, Ion-Exchange	A	1	1	1	N	N
62035	Agglutination Method, Human Chorionic Gonadotropin	B	2a	2	2	N	N
62036	Alcohol Control Materials	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62037	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method	B	2a	2	2	N	N
62038	Alizarin Sulfonate, Calcium	B	2a	2	2	N	N
62039	Alkaline Picrate, Colorimetry, Creatinine	B	2a	2	2	N	N
62040	Alpha-Naphthyl Phosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62041	Amikacin Serum Assay	B	2a	2	2	N	N
62042	Ammonium Molybdate And Ammonium Vanadate, Phospholipids	B	2a	2	1	N	N
62043	Amyloclastic, Amylase	B	2a	2	2	N	N
62044	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use	B	2a	2	1	N	N
62045	Analyzer, Chemistry (Sequential Multiple, Continuous Flow) Clinical Use	B	2a	2	1	N	N
62046	Analyzer, Chemistry, Centrifugal, For Clinical Use	B	2a	2	1	N	N
62047	Analyzer, Chemistry, Micro, For Clinical Use	B	2a	2	1	N	N
62048	Analyzer, Enzyme, For Clinical Use	B	2a	2	1	N	N
62049	Antiserum, Digitoxin	B	2a	2	2	N	N
62050	Antiserum, Digoxin	B	2a	2	2	N	N
62051	Antiserum, Gentamicin	B	2a	2	2	N	N
62052	Apolipoproteins	B	2a	2	1	N	N
62053	Apparatus, Electrophoresis, For Clinical Use	B	2a	2	1	N	N
62054	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	A	1	1	1	N	N
62055	Apparatus, High Pressure Liquid Chromatography	A	1	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62056	Artificial Pancreas Device System, Bihormonal Control	C	2b	3	3	N	N
62057	Artificial Pancreas Device System, Single Hormonal Control	D	3	3	3	N	N
62058	Artificial Pancreas Device System, Threshold Suspend	C	2b	3	3	N	N
62059	Assay, Porphyrin, Spectrophotometry, Lithium	B	2a	2	2	N	N
62060	Atomic Absorption Spectrophotometer, General Use	A	1	2	1	N	N
62061	Atomic Absorption, Antimony	B	2a	2	1	N	N
62062	Atomic Absorption, Arsenic	D	3	2	1	N	N
62063	Atomic Absorption, Calcium	B	2a	2	2	N	N
62064	Atomic Absorption, Iron (Non-Heme)	B	2a	2	1	N	N
62065	Atomic Absorption, Lithium	B	2a	2	2	N	N
62066	Atomic Absorption, Magnesium	B	2a	2	1	N	N
62067	Atomizer, Tlc	A	1	1	1	N	N
62068	Atp And Creatine Kinase (Enzymatic), Creatine	B	2a	2	1	N	N
62069	Automated Radioimmunoassay Systems, For Clinical Use	B	2a	2	1	N	N
62070	Automated Urinalysis System	B	2a	2	1	N	N
62071	Azo Dye, Calcium	B	2a	2	2	N	N
62072	Azo-Dyes, Colorimetric, Bilirubin & Its Conjugates (Urinary, Non-Quant.)	B	2a	2	1	N	N
62073	Bacillus Subtlis Microbiology Assay, Tobramycin	B	2a	2	2	N	N
62074	Bacillus Subtlis, Microbiological Assay, Gentamicin	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62075	Balance, Analytical	B	2a	2	1	N	N
62076	Bathophenanthroline, Colorimetry, Iron (Non-Heme)	B	2a	2	1	N	N
62077	Bathophenanthroline, Iron Binding Capacity	B	2a	2	1	N	N
62078	Berthelot Indophenol, Urea Nitrogen	B	3	2	2	N	N
62079	Beta Glycerophosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62080	Beta-D-Fructose & Nadh Oxidation (U.V.), Sorbitol Dehydrogenase	B	2a	2	1	N	N
62081	Bilirubin (Total And Unbound) In The Neonate Test System	B	2a	2	1	N	N
62082	Biosensor, Immunoassay, Cpk Or Isoenzymes	C	2b	3	2	N	N
62083	Biuret (Colorimetric), Total Protein	B	2a	2	2	N	N
62084	Blender/Mixer	D	3	1	1	N	N
62085	Block, Heating	B	2a	2	1	N	N
62086	Blood Alcohol Kit (Excludes Hiv Testing)	B	2a	2	2	N	N
62087	Blood And Urine Collection Kit (Excludes Hiv Testing)	D	3	1	1	N	N
62088	Breast Milk-Alcohol Test System	D	3	2	2	N	N
62089	Bromcresol Green Dye-Binding, Albumin	B	2a	2	2	N	N
62090	Bromcresol Purple Dye-Binding, Albumin	B	2a	2	2	N	N
62091	Calculator/Data Processing Module, For Clinical Use	B	2a	2	1	N	N
62092	Calibrator, Multi-Analyte Mixture	B	2a	2	2	N	N
62093	Calibrator, Primary	B	2a	2	2	N	N
62094	Calibrator, Secondary	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62095	Calibrator, Surrogate	D	3	2	2	N	N
62096	Calibrators, Drug Mixture	B	2a	2	2	N	N
62097	Calibrators, Drug Specific	B	2a	2	2	N	N
62098	Calibrators, Ethyl Alcohol	B	2a	2	2	N	N
62099	Cardiac Allograft Gene Expression Profiling Test System	C	2b	3	2	N	N
62100	Catalytic Methods, Amylase	B	2a	2	2	N	N
62101	Centrifuges (Micro, Ultra, Refrigerated) For Clinical Use	B	3	2	1	N	N
62102	Cholinesterase Test Paper	B	2a	2	1	N	N
62103	Chromatographic Derivative, Total Lipids	B	2a	2	1	N	N
62104	Chromatographic Separation, Cpk Isoenzymes	C	2b	3	2	N	N
62105	Chromatographic Separation, Lactate Dehydrogenase Isoenzymes	B	2a	2	2	N	N
62106	Chromatographic Separation, Lecithin/Sphingomyelin Ratio	B	2a	2	2	N	N
62107	Chromatographic Separation/Radioimmunoassay, Aldosterone	B	2a	2	2	N	N
62108	Chromatographic Separation/Zimmerman, 17-Ketosteroids	B	2a	2	1	N	N
62109	Chromatographic, Cystine	B	2a	2	1	N	N
62110	Chromatographic, Glutathione	B	2a	2	1	N	N
62111	Chromatographic, Histidine	B	2a	2	1	N	N
62112	Chromatographic, Phospholipids	B	2a	2	1	N	N
62113	Chromatographic/Fluorometric Method, Catecholamines	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62114	Chromatography (Liquid, Gel), Clinical Use	A	1	2	1	N	N
62115	Chromatography (Thin Layer), Clinical Use	A	1	2	1	N	N
62116	Chromatography For Bacterial Identification	A	1	1	1	N	N
62117	Chromatography Separation/Zimmerman 17-Ketogenic Steroids	B	2a	2	1	N	N
62118	Chromatography(Gas), Clinical Use	A	1	2	1	N	N
62119	Chromium-51, Blood Volume	B	2a	2	1	N	N
62120	Chromogenesis, Phenylketones (Urinary, Non-Quant.)	B	2a	2	1	N	N
62121	Citrulline, Arsenate, Nessler (Colorimetry), Ornithine Carbamyl Transferase	B	2a	2	1	N	N
62122	Clinical Sample Concentrator	B	2a	2	1	N	N
62123	Coating, Liquid, Glc	A	1	1	1	N	N
62124	Colorimeter, Photometer, Spectrophotometer For Clinical Use	B	2a	2	1	N	N
62125	Colorimetric Method, Cpk Or Isoenzymes	C	2b	3	2	N	N
62126	Colorimetric Method, Galactose	B	2a	2	1	N	N
62127	Colorimetric Method, Gamma-Glutamyl Transpeptidase	B	2a	2	1	N	N
62128	Colorimetric Method, Lecithin/Sphingomyelin Ratio	B	2a	2	2	N	N
62129	Colorimetric Method, Lipoproteins	B	2a	2	1	N	N
62130	Colorimetric Method, Triglycerides	B	2a	2	1	N	N
62131	Colorimetric, Mucopolysaccharides	B	2a	2	1	N	N
62132	Colorimetric, Xylose	B	2a	2	1	N	N
62133	Colorimetry, Acetaminophen	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62134	Colorimetry, Cholinesterase	B	2a	2	1	N	N
62135	Colorimetry, Salicylate	B	2a	2	2	N	N
62136	Column Chromatography & Color Development, Hydroxyproline	B	2a	2	1	N	N
62137	Column Or Paper Chromatography Plus Ninhydrin, Phenylalanine	B	2a	2	2	N	N
62138	Column Supports, Glc	B	2a	2	1	N	N
62139	Columns, Glc	B	2a	2	1	N	N
62140	Columns, Liquid Chromatography	D	3	1	1	N	N
62141	Comparison Of Freezing Points & Stds. Of Known Osmotic Pressure, Osmolality	B	2a	2	1	N	N
62142	Complete Gene Expression Profiling Accessory Reagents	B	2a	2	2	N	N
62143	Conductivity Rate, Urea Nitrogen	B	2a	2	2	N	N
62144	Controls For Blood-Gases, (Assayed And Unassayed)	B	2a	2	1	N	N
62145	Conversion To Creatinine, Creatine	B	2a	2	1	N	N
62146	Conversion To Ferric Hydroxymates (Colorimetric), Fatty Acids	B	2a	2	1	N	N
62147	Copper Reduction, Glucose	B	2a	2	2	N	N
62148	Coulometric Method, Carbon-Dioxide	B	2a	2	2	N	N
62149	Coulometric, Chloride	B	2a	2	2	N	N
62150	Counter (Beta, Gamma) For Clinical Use	B	2a	2	1	N	N
62151	Cresol Red Colorimetry, Carbon-Dioxide	B	2a	2	2	N	N
62152	Cresolphthalein Complexone, Calcium	B	2a	2	2	N	N
62153	Curvette, Thermostated	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62154	Cyclosporine	C	2b	3	2	N	N
62155	Cyclosporine And Metabolites Serum Assay	C	2b	3	2	N	N
62156	Cyclosporine Radioimmunoassay	C	2b	3	2	N	N
62157	Cytochrome P450 2c9 (Cyp450 2c9) Drug Metabolizing Enzyme Genotyping System	C	2b	3	2	N	N
62158	Delayed Analysis, Alcohol	B	2a	2	2	N	N
62159	Densitometer/Scanner (Integrating, Reflectance, Tlc, Radiochromat.) Clinica	B	2a	2	1	N	N
62160	Densitometric, Protein Fractionation	B	2a	2	1	N	N
62161	Detectors, Electrochemical, Liquid Chromatography	A	1	2	1	N	N
62162	Devices, Breath Trapping, Alcohol	B	2a	2	1	N	N
62163	Di (O-Hydroxyphenylimine) Ethane, Calcium	B	2a	2	2	N	N
62164	Diacetyl-Monoxime, Urea Nitrogen	B	2a	2	2	N	N
62165	Diagnostic Software, K-Nearest Neighbor Algorithm, Autoimmune Disease	B	2a	2	2	N	N
62166	Dialyzer	B	2a	2	1	N	N
62167	Diazo (Colorimetric), Nitrite (Urinary, Non-Quant)	B	2a	2	1	N	N
62168	Diazo Colorimetry, Bilirubin	B	3	2	2	N	N
62169	Diazo, Alt/Sgpt	B	3	2	1	N	N
62170	Diazo, Ast/Sgot	B	3	2	2	N	N
62171	Diazonium Colorimetry, Urobilinogen (Urinary, Non-Quant.)	B	3	2	1	N	N
62172	Diethyldithiocarbamate (Colorimetric), Copper	B	3	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62173	Differential Rate Kinetic Method, Cpk Or Isoenzymes	C	3	3	2	N	N
62174	Differential Rate Kinetic Method, Lactate Dehydrogenase Isoenzymes	B	3	2	2	N	N
62175	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System	A	3	1	1	N	N
62176	Digitoxin Control Serum, Ria	B	3	2	1	N	N
62177	Digoxin Control Serum, Ria	B	3	2	1	N	N
62178	Dinitrophenyl Hydrazone Measurement (Colorimetric), Hydroxybutyric Dehydroge	B	2a	2	1	N	N
62179	Disodium Phenylphosphate, Alkaline Phosphatase Or Isoenzymes	B	3	2	2	N	N
62180	Dna Specimen Collection, Saliva	B	3	2	2	N	N
62181	Drink, Glucose Tolerance	B	3	2	2	N	N
62182	Drug Metabolizing Enzyme Genotyping Systems	C	3	3	2	N	N
62183	Drug Mixture Control Materials	B	3	2	1	N	N
62184	Drug Specific Control Materials	B	3	2	1	N	N
62185	Dry Ash Method, Protein-Bound Iodine	B	3	2	1	N	N
62186	Dye-Indicator, Ph (Urinary, Non-Quant.)	D	3	2	1	N	N
62187	Eas Chromatography, Quinine	B	3	2	1	N	N
62188	Electrode Measurement, Blood-Gases (Pco2, Po2) And Blood Ph	B	3	2	2	N	N
62189	Electrode, Ion Based, Enzymatic, Creatinine	B	3	2	2	N	N
62190	Electrode, Ion Selective (Non-Specified)	B	3	2	1	N	N
62191	Electrode, Ion Specific, Calcium	B	3	2	2	N	N
62192	Electrode, Ion Specific, Magnesium	B	3	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62193	Electrode, Ion Specific, Potassium	B	2a	2	2	N	N
62194	Electrode, Ion Specific, Sodium	B	2a	2	2	N	N
62195	Electrode, Ion Specific, Urea Nitrogen	B	2a	2	2	N	N
62196	Electrode, Ion-Specific Method, Ammonia	B	2a	2	1	N	N
62197	Electrode, Ion-Specific, Chloride	B	3	2	2	N	N
62198	Electrolyte Controls (Assayed And Unassayed)	B	2a	2	1	N	N
62199	Electrometry, Cholinesterase	B	2a	2	1	N	N
62200	Electrophoresis, Cholesterol Via Esterase-Oxidase, Hdl	B	2a	2	1	N	N
62201	Electrophoretic Method, Catecholamines	B	2a	2	1	N	N
62202	Electrophoretic Method, Lecithin/Sphingomyelin Ratio	B	2a	2	2	N	N
62203	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes	B	2a	2	2	N	N
62204	Electrophoretic Separation, Lipoproteins	B	2a	2	1	N	N
62205	Electrophoretic, Gamma-Glutamyl Transpeptidase Isoenzymes	B	2a	2	1	N	N
62206	Electrophoretic, Globulin	B	2a	2	1	N	N
62207	Electrophoretic, Lactate Dehydrogenase Isoenzymes	B	2a	2	2	N	N
62208	Electrophoretic, Protein Fractionation	B	2a	2	1	N	N
62209	Enzymatic (Glutathione Reductase), Glutathione	B	2a	2	1	N	N
62210	Enzymatic Esterase--Oxidase, Cholesterol	B	2a	2	1	N	N
62211	Enzymatic Method, Alcohol Dehydrogenase, Ultraviolet	B	2a	2	2	N	N
62212	Enzymatic Method, Ammonia	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62213	Enzymatic Method, Bilirubin	B	2a	2	2	N	N
62214	Enzymatic Method, Creatinine	B	2a	2	2	N	N
62215	Enzymatic Methods, Galactose	B	2a	2	1	N	N
62216	Enzymatic Radiochemical Assay, Amikacin	B	2a	2	2	N	N
62217	Enzymatic Radiochemical Assay, Gentamicin	B	2a	2	2	N	N
62218	Enzymatic Radiochemical Assay, Tobramycin	B	2a	2	2	N	N
62219	Enzymatic, Carbon-Dioxide	B	2a	2	2	N	N
62220	Enzymatic, Carbon-Dioxide	B	2a	2	2	N	N
62221	Enzyme Controls (Assayed And Unassayed)	B	2a	2	1	N	N
62222	Enzyme Immunoassay, Nicotine And Nicotine Metabolites	B	2a	2	1	N	N
62223	Enzyme Immunoassay, Amphetamine	B	2a	2	2	N	N
62224	Enzyme Immunoassay, Barbiturate	B	2a	2	2	N	N
62225	Enzyme Immunoassay, Benzodiazepine	B	2a	2	2	N	N
62226	Enzyme Immunoassay, Cannabinoids	B	2a	2	2	N	N
62227	Enzyme Immunoassay, Carbamazepine	B	2a	2	2	N	N
62228	Enzyme Immunoassay, Cocaine	B	2a	2	2	N	N
62229	Enzyme Immunoassay, Cocaine And Cocaine Metabolites	B	2a	2	2	N	N
62230	Enzyme Immunoassay, Cortisol, Salivary	B	2a	2	2	N	N
62231	Enzyme Immunoassay, Digitoxin	B	2a	2	2	N	N
62232	Enzyme Immunoassay, Digoxin	B	2a	2	2	N	N
62233	Enzyme Immunoassay, Diphenylhydantoin	B	2a	2	2	N	N
62234	Enzyme Immunoassay, Ethosuximide	B	2a	2	2	N	N
62235	Enzyme Immunoassay, Fetal Fibronectin	B	2a	2	3	N	N
62236	Enzyme Immunoassay, Gentamicin	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62237	Enzyme Immunoassay, Inhibin-A	B	2a	2	1	N	N
62238	Enzyme Immunoassay, Lidocaine	B	2a	2	2	N	N
62239	Enzyme Immunoassay, Methadone	B	2a	2	2	N	N
62240	Enzyme Immunoassay, N-Acetylprocainamide	B	2a	2	2	N	N
62241	Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine	B	2a	2	2	N	N
62242	Enzyme Immunoassay, Opiates	B	2a	2	2	N	N
62243	Enzyme Immunoassay, Phencyclidine	B	2a	2	2	N	N
62244	Enzyme Immunoassay, Phenobarbital	B	2a	2	2	N	N
62245	Enzyme Immunoassay, Primidone	B	2a	2	2	N	N
62246	Enzyme Immunoassay, Procainamide	B	2a	2	2	N	N
62247	Enzyme Immunoassay, Propoxyphene	B	2a	2	2	N	N
62248	Enzyme Immunoassay, Quinidine	B	2a	2	2	N	N
62249	Enzyme Immunoassay, Theophylline	B	2a	2	2	N	N
62250	Enzyme Immunoassay, Tracrolimus	C	2b	3	2	N	N
62251	Enzyme Immunoassay, Valproic Acid	B	2a	2	2	N	N
62252	Equipment, Laboratory, General Purpose, Labeled Or Promoted For A Specific Medical Use	A	1	1	1	N	N
62253	Evaporator	D	1	1	1	N	N
62254	Everolimus Immunoassay	D	2a	2	2	N	N
62255	Extraction Plus Chromatography With Color By Ninhydrin, Hydroxyproline	D	2a	2	1	N	N
62256	Ferric Chloride, Phenylketones (Urinary, Non-Quant.)	D	2a	2	1	N	N
62257	Ferricyanide, Glucose	D	2a	2	2	N	N
62258	Ferrozine (Colorimetric) Iron Binding Capacity	D	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62259	Flame Emission Photometer For Clinical Use	D	2a	2	1	N	N
62260	Flame Photometry, Lithium	D	2a	2	2	N	N
62261	Flame Photometry, Potassium	B	2a	2	2	N	N
62262	Flame Photometry, Sodium	B	2a	2	2	N	N
62263	Fluorescence Polarization Immunoassay, Amibacin	B	2a	2	2	N	N
62264	Fluorescence Polarization Immunoassay, Carbamazepine	B	2a	2	2	N	N
62265	Fluorescence Polarization Immunoassay, Diphenylhydantoin (Free)	B	2a	2	2	N	N
62266	Fluorescence Polarization Immunoassay, Diphenylhydantoin (Total)	B	2a	2	2	N	N
62267	Fluorescence Polarization Immunoassay, Phenobarbital	B	2a	2	2	N	N
62268	Fluorescence Polarization Immunoassay, Theophylline	B	2a	2	2	N	N
62269	Fluorescence Polarization Immunoassay, Tobramycin	B	2a	2	2	N	N
62270	Fluorescent Immunoassay Gentamicin	B	2a	2	2	N	N
62271	Fluorescent Immunoassay, Diphenylhydantoin	B	2a	2	2	N	N
62272	Fluorescent Immunoassay, Phenobarbital	B	2a	2	2	N	N
62273	Fluorescent Immunoassay, Primidone	B	2a	2	2	N	N
62274	Fluorescent Immunoassay, Theophylline	B	2a	2	2	N	N
62275	Fluorescent Immunoassay, Tobramycin	B	2a	2	2	N	N
62276	Fluorescent Proc. (Qual.), Galactose-1-Phosphate Uridyl Transferase	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62277	Fluorometer, For Clinical Use	B	2a	2	1	N	N
62278	Fluorometer, Lead (Dedicated Instruments)	B	2a	2	2	N	N
62279	Fluorometric Measurement, Porphyrins	B	2a	2	1	N	N
62280	Fluorometric Method, 17-Hydroxycorticosteroids	B	2a	2	1	N	N
62281	Fluorometric Method, Cpk Or Isoenzymes	C	2b	3	2	N	N
62282	Fluorometric Method, Triglycerides	B	2a	2	1	N	N
62283	Fluorometric, Calcium	B	2a	2	2	N	N
62284	Fluorometric, Cortisol	B	2a	2	2	N	N
62285	Fluorometric, Uroporphyrin	B	2a	2	1	N	N
62286	Fluorometry, Morphine	B	2a	2	2	N	N
62287	Fluorescence Polarization Immunoassay For Cyclosporine	C	2b	3	2	N	N
62288	Free Radical Assay, Amphetamine	B	2a	2	2	N	N
62289	Free Radical Assay, Cocaine	B	2a	2	2	N	N
62290	Free Radical Assay, Lsd	B	2a	2	2	N	N
62291	Free Radical Assay, Methadone	B	2a	2	2	N	N
62292	Free Radical Assay, Morphine	B	2a	2	2	N	N
62293	Free Radical Assay, Opiates	B	2a	2	2	N	N
62294	Free Radical, Benzoylcegonine	B	2a	2	2	N	N
62295	Freezer	A	1	1	1	N	N
62296	Fructose-1, 6-Diphosphate And Nadh (U.V.), Aldolase	B	2a	2	1	N	N
62297	Gabapentin Assay	B	2a	2	2	N	N
62298	Galectin-3 In Vitro Diagnostic Assay	C	2b	3	2	N	N
62299	Gas Chromatograph, Alcohol (Dedicated Instruments)	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62300	Gas Chromatograph, Carbon-Monoxide	B	2a	2	1	N	N
62301	Gas Chromatography, Alcohol	B	2a	2	2	N	N
62302	Gas Chromatography, Amphetamine	B	2a	2	2	N	N
62303	Gas Chromatography, Benzodiazepine	B	2a	2	2	N	N
62304	Gas Chromatography, Cocaine	B	2a	2	2	N	N
62305	Gas Chromatography, Codeine	B	2a	2	2	N	N
62306	Gas Chromatography, Diphenylhydantoin	B	2a	2	2	N	N
62307	Gas Chromatography, Ethosuximide	B	2a	2	2	N	N
62308	Gas Chromatography, Methadone	B	2a	2	2	N	N
62309	Gas Chromatography, Methamphetamine	B	2a	2	2	N	N
62310	Gas Chromatography, Morphine	B	2a	2	2	N	N
62311	Gas Chromatography, Opiates	B	2a	2	2	N	N
62312	Gas Chromatography, Phenobarbital	B	2a	2	2	N	N
62313	Gas Chromatography, Pregnanetriol	B	2a	2	1	N	N
62314	Gas Chromatography, Primidone	B	2a	2	2	N	N
62315	Gas Chromatography, Propoxyphene	B	2a	2	2	N	N
62316	Gas Chromatography, Salicylate	B	2a	2	2	N	N
62317	Gas Liquid Chromatography, Barbiturate	B	2a	2	2	N	N
62318	Gases, Glc	A	1	1	1	N	N
62319	Glucose Dehydrogenase, Glucose	B	2a	2	2	N	N
62320	Glucose Oxidase, Glucose	B	2a	2	2	N	N
62321	Glucose-6-Phosphate (Colorimetric), Phosphohexose Isomerase	B	2a	2	1	N	N
62322	Glyceralde-3-Phosphate, Nadh (Enzymatic), Triose Phosphate Isomerase	B	2a	2	1	N	N
62323	Gold Chloride (Colorimetric), Bromide	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62324	Heavy Metals Control Materials	B	2a	2	1	N	N
62325	Hemagglutination Inhibition, Barbiturate	B	2a	2	2	N	N
62326	Hemagglutination Inhibition, Gentamicin	B	2a	2	2	N	N
62327	Hemagglutination Inhibition, Methadone	B	2a	2	2	N	N
62328	Hemagglutination Inhibition, Morphine	B	2a	2	2	N	N
62329	Hemagglutination, Cocaine Metabolites (Benzoylcegonine)	B	2a	2	2	N	N
62330	Hemagglutination, Opiates	B	2a	2	2	N	N
62331	Hexane Extraction, Fluorescence, Vitamin E	B	2a	2	1	N	N
62332	Hexokinase, Glucose	B	2a	2	2	N	N
62333	High Performance Liquid Chromatography For Cyclosporine	C	2b	3	2	N	N
62334	High Performance Liquid Chromatography For Cyclosporine	C	2b	3	2	N	N
62335	High Pressure Liquid Chromatography, Barbiturate	B	2a	2	2	N	N
62336	High Pressure Liquid Chromatography, Benzodiazepine	B	2a	2	2	N	N
62337	High Pressure Liquid Chromatography, Cocaine And Cocaine Metabolites	B	2a	2	2	N	N
62338	High Pressure Liquid Chromatography, Codeine	B	2a	2	2	N	N
62339	High Pressure Liquid Chromatography, Methamphetamine	B	2a	2	2	N	N
62340	High Pressure Liquid Chromatography, Opiates	B	2a	2	2	N	N
62341	High Pressure Liquid Chromatography, Propoxyphene	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62342	High Pressure Liquid Chromatography, Quinine	B	2a	2	1	N	N
62343	High Pressure Liquid Chromatography, Tricyclic Antidepressant Drugs	B	2a	2	2	N	N
62344	Hyaline Membrane Disease Assay	B	2a	2	3	N	N
62345	Hydrazone Colorimetry, Aldolase	B	2a	2	1	N	N
62346	Hydrazone Colorimetry, Alt/Sgpt	B	2a	2	1	N	N
62347	Hydrazone Colorimetry, Ast/Sgot	B	2a	2	2	N	N
62348	Hydrazone Deriv. Of Alpha-Ketogluterate (Colorimetry), Isocitric Dehydrogen	B	2a	2	1	N	N
62349	Immunoassay For Detection Of Amniotic Fluid Protein(S).	B	2a	2	1	N	N
62350	Immunoassay Method, Troponin Subunit	C	2b	3	2	N	N
62351	Immunoassay, Anti-Seizure Drug	B	2a	2	2	N	N
62352	Immunoassay, Insulin-Like Growth Factor Binding Protein-1	B	2a	2	1	N	N
62353	Immunochemical, Lysozyme (Muramidase)	B	2a	2	1	N	N
62354	Immunodiffusion, Protein Fractionation	B	2a	2	1	N	N
62355	Indicator Method, Protein Or Albumin (Urinary, Non-Quant.)	B	2a	2	1	N	N
62356	Indicator, Alumina Fluorescent, Tlc	A	1	1	1	N	N
62357	Indicator, Cellulose Fluorescent, Tlc	B	2a	2	1	N	N
62358	Indicator, Silica Gel Fluorescent, Tlc	A	1	1	1	N	N
62359	Infrared Spectroscopy Measurement, Urinary Calculi (Stone)	B	2a	2	1	N	N
62360	Instrument, Glucose, Noninvasive Technology	B	2a	2	3	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62361	Instrumentation For Clinical Multiplex Test Systems	B	2a	2	2	N	N
62362	Instrumentation, High Pressure Liquid Chromatography	A	1	2	1	N	N
62363	Internal Polymerase Chain Reaction Control, Not Assay Specific	B	2a	2	1	N	N
62364	Ion-Exchange Chromatography	A	1	1	1	N	N
62365	Ion-Exchange Resin, Ehrlich'S Reagent, Porphobilinogen	B	2a	2	1	N	N
62366	Kinetic Method, Gamma-Glutamyl Transpeptidase	B	2a	2	1	N	N
62367	Kit, Direct Antigen, Negative Control	B	2a	2	1	N	N
62368	Kit, Direct Antigen, Positive Control	B	2a	2	1	N	N
62369	Kit, Disc, Agar Gel Diffusion, Determine Serum Levels Of Gentamicin	B	2a	2	2	N	N
62370	Kit, Disc, Agar Gel Diffusion, Determine Serum Levels Of Kanamycin	B	2a	2	2	N	N
62371	Kit, Disc, Agar Gel Diffusion, Determine Serum Levels Of Tobramycin	B	2a	2	2	N	N
62372	Kit, Serological, Negative Control	B	2a	2	1	N	N
62373	Kit, Serological, Positive Control	B	2a	2	1	N	N
62374	Kit, Test, Multiple, Drugs Of Abuse, Over The Counter	C	2b	3	U	N	N
62375	Kit, Test, Pregnancy, Hcg, Over The Counter	B	2a	2	2	N	N
62376	Lamotrigine Assay	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62377	Ldl & Vldl Precipitation, Cholesterol Via Esterase-Oxidase, Hdl	B	2a	2	1	N	N
62378	Ldl & Vldl Precipitation, Hdl	B	2a	2	1	N	N
62379	Lead, Atomic Absorption	B	2a	2	2	N	N
62380	Lead, Delta Amino Levulinic Acid	B	2a	2	2	N	N
62381	Lead, Protoporphyrin Zinc Method, Fluorometric	B	2a	2	2	N	N
62382	Lead, Protoporphyrin, Fluorometric	B	2a	2	2	N	N
62383	Levetiracetam Assay	B	2a	2	2	N	N
62384	Lidocaine Control Materials	B	2a	2	1	N	N
62385	Lieberman-Burchard/Abell-Kendall, Colorimetric, Cholesterol	B	2a	2	1	N	N
62386	Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides	B	2a	2	1	N	N
62387	Lipase-Esterase, Enzymatic, Photometric, Lipase	B	2a	2	1	N	N
62388	Lipoprotein, High Density, Hdl, Over The Counter	B	2a	2	1	N	N
62389	Liquid Chromatography, Adsorbent	A	1	1	1	N	N
62390	Liquid Chromatography, Amphetamine	B	2a	2	2	N	N
62391	Liquid Chromatography, Diphenylhydantoin	B	2a	2	2	N	N
62392	Liquid Chromatography, Ethosuximide	B	2a	2	2	N	N
62393	Liquid Chromatography, Methadone	B	2a	2	2	N	N
62394	Liquid Chromatography, Morphine	B	2a	2	2	N	N
62395	Liquid Chromatography, Phenobarbital	B	2a	2	2	N	N
62396	Liquid Chromatography, Primidone	B	2a	2	2	N	N
62397	Liquid Chromatography, Salicylate	B	2a	2	2	N	N
62398	L-Isocitrate And Nadp (U.V.), Isocitric Dehydrogenase	B	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62399	L-Leucine-4-Nitroanilide (Colorimetric), Leucine Arylamidase	B	2a	2	1	N	N
62400	L-Leucyl B-Naphthylamide, Leucine Aminopeptidase	B	2a	2	1	N	N
62401	Lowry (Colorimetric), Total Protein	B	2a	2	2	N	N
62402	M. Lysodeikticus Cells (Spectrophotometric), Lysozyme (Muramidase)	B	2a	2	1	N	N
62403	Mass Spectrometer For Clinical Multiplex Test Systems	B	2a	2	2	N	N
62404	Mass Spectrometer, Clinical Use	A	1	1	1	N	N
62405	Membrane Osmometry, Plasma Oncometry	B	2a	2	1	N	N
62406	Mercuric Nitrate And Diphenyl Carbazone (Titrimetric), Chloride	B	2a	2	2	N	N
62407	Mercuric Thiocyanate, Colorimetry, Chloride	B	2a	2	2	N	N
62408	Mercury Dithiazone, Colorimetry, Barbiturate	B	2a	2	2	N	N
62409	Mercury, Atomic Absorption	B	2a	2	1	N	N
62410	Method, Enzymatic, Glucose (Urinary, Non-Quantitative)	B	2a	2	2	N	N
62411	Method, Ion-Exchange, Ammonia	B	2a	2	1	N	N
62412	Method, Metallic Reduction, Glucose (Urinary, Non-Quantitative)	B	2a	2	2	N	N
62413	Methotrexate Control Materials	B	2a	2	1	N	N
62414	Methylthymol Blue, Calcium	B	2a	2	2	N	N
62415	Micro Mixer	A	1	1	1	N	N
62416	Micro Pipette	A	1	1	1	N	N
62417	Micro Total Analysis Instrument System	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62418	Microbiological, Histidine	B	2a	2	1	N	N
62419	Microdensitometry Method, Lipoproteins	B	2a	2	1	N	N
62420	Microtitrator, For Clinical Use	B	2a	2	1	N	N
62421	Mixer, Blood Tube	A	1	1	1	N	N
62422	Molybdenum Blue Method, Phospholipids	B	2a	2	1	N	N
62423	Monitor, U.V., Glc	A	1	2	1	N	N
62424	Multi-Analyte Controls Unassayed	B	2a	2	1	N	N
62425	Multi-Analyte Controls, All Kinds (Assayed)	B	2a	2	1	N	N
62426	Mycophenolic Acid Test System	B	2a	2	2	N	N
62427	N-Acetyl-L-Tyrosine Ethyl Ester (U.V.), Chymotrypsin	B	2a	2	1	N	N
62428	N-Acetylprocainamide Control Materials	B	2a	2	1	N	N
62429	Nad Reduction (U.V.), Phosphohexose Isomerase	B	2a	2	1	N	N
62430	Nad Reduction/Nadh Oxidation, Cpk Or Isoenzymes	C	2b	3	2	N	N
62431	Nad Reduction/Nadh Oxidation, Lactate Dehydrogenase	B	2a	2	2	N	N
62432	Nadh Oxidation/Nad Reduction, Alt/Sgpt	B	2a	2	1	N	N
62433	Nadh Oxidation/Nad Reduction, Ast/Sgot	B	2a	2	2	N	N
62434	Nadh, Phosphoglycerate Mutase, Atp (U.V.) 2,3-Diphosphoglyceric Acid	B	2a	2	1	N	N
62435	Nad-Nadh, Specific Reagent For Alcohol Enzyme Method	B	2a	2	2	N	N
62436	Nadp Reduction, 6-Phosphogluconate Dehydrogenase	B	2a	2	1	N	N
62437	N-Benzoyl-L-Arginine Ethyl Ester (U.V.), Trypsin	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62438	N-Benzoyl-L-Tyrosine Ethyl Ester (U.V.), Chymotrypsin	B	2a	2	1	N	N
62439	Neonatal Blood Collection Kit And Screening Form (Excludes Hiv Testing)	B	2a	2	1	N	N
62440	Nephelometer, For Clinical Use	B	2a	2	1	N	N
62441	Nephelometric Inhibition Immunoassay, Diphenylhydantoin	B	2a	2	2	N	N
62442	Nephelometric Inhibition Immunoassay, Phenobarbital	B	2a	2	2	N	N
62443	Nephelometric Method, Globulin	B	2a	2	1	N	N
62444	Nephelometric Method, Lipoproteins	B	2a	2	1	N	N
62445	Nephelometric, Amylase	B	2a	2	2	N	N
62446	Ninhydrin And L-Leucyl-L-Alanine (Fluorimetric), Phenylalanine	B	2a	2	2	N	N
62447	Ninhydrin, Nitrogen (Amino-Nitrogen)	B	2a	2	1	N	N
62448	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62449	Nitroprusside Reaction (Qualitative, Urine), Cystine	B	2a	2	1	N	N
62450	Nitroprusside, Ketones (Urinary, Non-Quant.)	B	2a	2	1	N	N
62451	Nitrosalicylate Reduction, Amylase	B	2a	2	2	N	N
62452	Oil Emulsion/Thymolphthalein (Titrimetric), Lipase	B	2a	2	1	N	N
62453	Olive Oil Emulsion (Turbidimetric), Lipase	B	2a	2	1	N	N
62454	Oncometer, Plasma, For Clinical Use	B	2a	2	1	N	N
62455	O-Phthalaldehyde, Urea Nitrogen	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62456	Orthotoluidine, Glucose	B	2a	2	2	N	N
62457	Osmolality Of Tears	B	2a	2	1	N	N
62458	Osmometer For Clinical Use	B	2a	2	1	N	N
62459	Oxalydihydrazide (Spectroscopic), Copper	B	2a	2	1	N	N
62460	Papers, Ion	A	1	1	1	N	N
62461	Paraquat Assay	B	2a	2	3	N	N
62462	P-Bromoaniline, Xylose	B	2a	2	1	N	N
62463	Ph Meter	B	2a	2	1	N	N
62464	Ph Rate Measurement, Carbon-Dioxide	B	2a	2	2	N	N
62465	Phenolphthalein Colorimetry, Carbon-Dioxide	B	2a	2	2	N	N
62466	Phenolphthalein Phosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62467	Phenylphosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62468	Phosphoenol Pyruvate, Adp, Nadh, Pyruvate Kinase	B	2a	2	1	N	N
62469	Phosphoglycerate Mutase (Colorimetric), 2,3-Diphosphoglyceric Acid	B	2a	2	1	N	N
62470	Phosphomolybdate (Colorimetric), Inorganic Phosphorus	B	2a	2	1	N	N
62471	Photometric Method, Ammonia	B	2a	2	1	N	N
62472	Photometric Method, Iron (Non-Heme)	B	2a	2	1	N	N
62473	Photometric Method, Magnesium	B	2a	2	1	N	N
62474	Plasma Viscometer For Clinical Use	B	2a	2	1	N	N
62475	Plate, Alumina, Tlc	A	1	1	1	N	N
62476	Plate, Cellulose, Tlc	A	1	1	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62477	Plate, Silica Gel, Tlc	A	1	1	1	N	N
62478	Polarimeter	B	2a	2	1	N	N
62479	Porter Silber Hydrazone, 17-Hydroxycorticosteroids	B	2a	2	1	N	N
62480	Potassium Dichromate Specific Reagent For Alcohol	B	2a	2	2	N	N
62481	Potassium Dichromate, Alcohol	B	2a	2	2	N	N
62482	Procainamide Control Materials	B	2a	2	1	N	N
62483	P-Toluenesulphonyl-L-Arginine Methyl Ester (U.V.), Trypsin	B	2a	2	1	N	N
62484	Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor	C	2b	3	3	N	N
62485	Purifier, Water (Absorption, Deionization, Membrane Filter, Reverse Osmosis)	B	2a	2	1	N	N
62486	Qualitative Chemical Reactions, Urinary Calculi (Stone)	B	2a	2	1	N	N
62487	Radial Diffusion, Amylase	B	2a	2	2	N	N
62488	Radial Immunodiffusion, Albumin	B	2a	2	2	N	N
62489	Radial Immunodiffusion, Lipoproteins	B	2a	2	1	N	N
62490	Radioassay, 17-Hydroxycorticosteroids	B	2a	2	1	N	N
62491	Radioassay, Angiotensin Converting Enzyme	B	2a	2	2	N	N
62492	Radioassay, Intrinsic Factor Blocking Antibody	B	2a	2	2	N	N
62493	Radioassay, Triiodothyronine Uptake	B	2a	2	2	N	N
62494	Radioassay, Vitamin B12	B	2a	2	2	N	N
62495	Radioceptor Assay, Neuroleptic Drugs	B	2a	2	2	N	N
62496	Radioimmunoassay For Cyclosporine	C	2b	3	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62497	Radioimmunoassay, 17-Hydroxyprogesterone	B	2a	2	1	N	N
62498	Radioimmunoassay, Acth	B	2a	2	2	N	N
62499	Radioimmunoassay, Aldosterone	B	2a	2	2	N	N
62500	Radioimmunoassay, Amikacin	B	2a	2	2	N	N
62501	Radioimmunoassay, Amphetamine	B	2a	2	2	N	N
62502	Radioimmunoassay, Amphetamine (125-I), Goat Antibody, Ammonium Sulfate Sep.	B	2a	2	2	N	N
62503	Radioimmunoassay, Androstenedione	B	2a	2	1	N	N
62504	Radioimmunoassay, Androsterone	B	2a	2	1	N	N
62505	Radioimmunoassay, Angiotensin I And Renin	B	2a	2	2	N	N
62506	Radioimmunoassay, Barbiturate	B	2a	2	2	N	N
62507	Radioimmunoassay, Calcitonin	B	2a	2	2	N	N
62508	Radioimmunoassay, Cannabinoid(S)	B	2a	2	2	N	N
62509	Radioimmunoassay, Cholyglycine, Bile Acids	B	2a	2	2	N	N
62510	Radioimmunoassay, Cocaine Metabolite	B	2a	2	2	N	N
62511	Radioimmunoassay, Compound S (11-Deoxycortisol)	B	2a	2	1	N	N
62512	Radioimmunoassay, Conjugated Sulfalithocholic (Slcg) Acid, Bile Acids	B	2a	2	2	N	N
62513	Radioimmunoassay, Corticoids	B	2a	2	1	N	N
62514	Radioimmunoassay, Corticosterone	B	2a	2	1	N	N
62515	Radioimmunoassay, Cortisol	B	2a	2	2	N	N
62516	Radioimmunoassay, C-Peptides Of Proinsulin	B	2a	2	1	N	N
62517	Radioimmunoassay, Cyclic Amp	B	2a	2	2	N	N
62518	Radioimmunoassay, Cyclic Gmp	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62519	Radioimmunoassay, Dehydroepiandrosterone (Free And Sulfate)	B	2a	2	1	N	N
62520	Radioimmunoassay, Desoxycorticosterone	B	2a	2	1	N	N
62521	Radioimmunoassay, Digitoxin (125-I)	B	2a	2	2	N	N
62522	Radioimmunoassay, Digitoxin (125-I), Bovine Antibody, Charcoal Sep.	B	2a	2	2	N	N
62523	Radioimmunoassay, Digitoxin (125-I), Rabbit Antibody, Coated Tube Sep.	B	2a	2	2	N	N
62524	Radioimmunoassay, Digitoxin (125-I), Rabbit Antibody, Solid Phase Sep.	B	2a	2	2	N	N
62525	Radioimmunoassay, Digitoxin (3-H)	B	2a	2	2	N	N
62526	Radioimmunoassay, Digitoxin (3-H), Rabbit Antibody, Charcoal Sep.	B	2a	2	2	N	N
62527	Radioimmunoassay, Digitoxin (3-H), Rabbit Antibody, Coated Tube	B	2a	2	2	N	N
62528	Radioimmunoassay, Digoxin (125-I)	B	2a	2	2	N	N
62529	Radioimmunoassay, Digoxin (125-I), Bovine Antibody, Charcoal Sep.	B	2a	2	2	N	N
62530	Radioimmunoassay, Digoxin (125-I), Goat Antibody, 2nd Antibody Sep.	B	2a	2	2	N	N
62531	Radioimmunoassay, Digoxin (125-I), Goat Antibody, Anion Exchange, Resin Sep.	B	2a	2	2	N	N
62532	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Charcoal Sep.	B	2a	2	2	N	N
62533	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Coated Tube Sep.	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62534	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Double Label Sep.	B	2a	2	2	N	N
62535	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Polyethylene Glycol	B	2a	2	2	N	N
62536	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Second Antibody Sep.	B	2a	2	2	N	N
62537	Radioimmunoassay, Digoxin (125-I), Rabbit Antibody, Solid Phase Sep.	B	2a	2	2	N	N
62538	Radioimmunoassay, Digoxin (3-H)	B	2a	2	2	N	N
62539	Radioimmunoassay, Digoxin (3-H), Bovine Antibody, Charcoal Sep.	B	2a	2	2	N	N
62540	Radioimmunoassay, Digoxin (3-H), Goat Antibody, 2nd Antibody Sep.	B	2a	2	2	N	N
62541	Radioimmunoassay, Digoxin (3-H), Rabbit Antibody, Charcoal Sep.	B	2a	2	2	N	N
62542	Radioimmunoassay, Digoxin (3-H), Rabbit Antibody, Coated Tubes Sep.	B	2a	2	2	N	N
62543	Radioimmunoassay, Diphenylhydantoin	B	2a	2	2	N	N
62544	Radioimmunoassay, Estradiol	B	2a	2	1	N	N
62545	Radioimmunoassay, Estriol	B	2a	2	1	N	N
62546	Radioimmunoassay, Estrone	B	2a	2	1	N	N
62547	Radioimmunoassay, Ethosuximide	B	2a	2	2	N	N
62548	Radioimmunoassay, Etiocholanolone	C	2b	3	1	N	N
62549	Radioimmunoassay, Follicle-Stimulating Hormone	B	2a	2	1	N	N
62550	Radioimmunoassay, Free Thyroxine	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62551	Radioimmunoassay, Gastrin	B	2a	2	1	N	N
62552	Radioimmunoassay, Gentamicin (125-I), Second Antibody Sep.	B	2a	2	2	N	N
62553	Radioimmunoassay, Glucagon	B	2a	2	1	N	N
62554	Radioimmunoassay, Human Growth Hormone	B	2a	2	1	N	N
62555	Radioimmunoassay, Human Placental Lactogen	B	2a	2	2	N	N
62556	Radioimmunoassay, Immunoreactive Insulin	B	2a	2	1	N	N
62557	Radioimmunoassay, Kanamycin	B	2a	2	2	N	N
62558	Radioimmunoassay, Lsd (125-I)	B	2a	2	2	N	N
62559	Radioimmunoassay, Luteinizing Hormone	B	2a	2	1	N	N
62560	Radioimmunoassay, Methaqualone	B	2a	2	2	N	N
62561	Radioimmunoassay, Morphine (125-I), Goat Antibody Ammonium Sulfate Sep.	B	2a	2	2	N	N
62562	Radioimmunoassay, Morphine (3-H), Goat Antibody Ammonium Sulfate Sep.	B	2a	2	2	N	N
62563	Radioimmunoassay, Morphine-Barbiturate (125-I), Goat Antibody	B	2a	2	2	N	N
62564	Radioimmunoassay, Parathyroid Hormone	B	2a	2	2	N	N
62565	Radioimmunoassay, Phencyclidine	B	2a	2	U	N	N
62566	Radioimmunoassay, Phenobarbital	B	2a	2	2	N	N
62567	Radioimmunoassay, Pregnenolone	B	2a	2	1	N	N
62568	Radioimmunoassay, Primidone	B	2a	2	2	N	N
62569	Radioimmunoassay, Progesterone	B	2a	2	1	N	N
62570	Radioimmunoassay, Prolactin (Lactogen)	B	2a	2	1	N	N
62571	Radioimmunoassay, Testosterones And Dihydrotestosterone	B	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62572	Radioimmunoassay, Theophylline	B	2a	2	2	N	N
62573	Radioimmunoassay, Thyroid-Stimulating Hormone	B	2a	2	2	N	N
62574	Radioimmunoassay, Thyroxine-Binding Globulin	B	2a	2	2	N	N
62575	Radioimmunoassay, Tobramycin	B	2a	2	2	N	N
62576	Radioimmunoassay, Total Estrogens In Pregnancy	B	2a	2	1	N	N
62577	Radioimmunoassay, Total Estrogens, Nonpregnancy	B	2a	2	1	N	N
62578	Radioimmunoassay, Total Thyroxine	B	2a	2	2	N	N
62579	Radioimmunoassay, Total Triiodothyronine	B	2a	2	2	N	N
62580	Radioimmunoassay, Tricyclic Antidepressant Drugs	B	2a	2	2	N	N
62581	Radioimmunoassay, Vancomycin	B	2a	2	2	N	N
62582	Radio-Labeled Iron Method, Iron (Non-Heme)	B	2a	2	1	N	N
62583	Radiometric, Fe59, Iron Binding Capacity	B	2a	2	1	N	N
62584	Radioreceptor Assay, Human Chorionic Gonadotropin	B	2a	2	2	N	N
62585	Reagents, Test, Bromides	B	2a	2	2	N	N
62586	Reagents, Test, Tetrahydrocannabinol	B	2a	2	2	N	N
62587	Real Time Nucleic Acid Amplification System	C	2b	3	2	N	N
62588	Refractometer For Clinical Use	B	2a	2	1	N	N
62589	Refractometric, Total Protein	B	2a	2	2	N	N
62590	Regulator, Temperature	B	2a	2	1	N	N
62591	Research Use Only/Clinical Chemistry Devices	U	U	U	U	N	N
62592	Research Use Only/Clinical Toxicology	U	U	U	U	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62593	Resin, Ion-Exchange, Ascorbic Acid, Colorimetry, Iron Binding Capacity	B	2a	2	1	N	N
62594	Resin, Ion-Exchange, Thioglycolic Acid, Colorimetry, Iron Binding Capacity	B	2a	2	1	N	N
62595	Resins, Ion-Exchange	A	1	2	1	N	N
62596	Resins, Ion-Exchange, Liquid Chromatography	A	1	1	1	N	N
62597	Rotating Disc, Plasma Viscometry	B	2a	2	1	N	N
62598	Saccharogenic, Amylase	B	2a	2	2	N	N
62599	Sensor, Glucose, Invasive	C	2b	3	3	N	N
62600	Shaker/Stirrer	A	1	1	1	N	N
62601	Single (Specified) Analyte Controls (Assayed And Unassayed)	B	2a	2	1	N	N
62602	Sirolimus Test System	B	2a	2	2	N	N
62603	Sodium Hydroxide And Phenol Red (Titrimetric), Gastric Acidity	B	2a	2	1	N	N
62604	Software, Similarity Score Algorithm, Tissue Of Origin For Malignant Tumor Types	C	2b	3	2	N	N
62605	Solution, M-Nitrophenol, Specific Reagent For Cholinesterase	B	2a	2	1	N	N
62606	Spectral Absorb. Curve, Oxyhemoglobin, Carboxyhemoglobin, Carbon-Monoxide	B	2a	2	1	N	N
62607	Spectrophotometric Method, Pregnanediol	B	2a	2	1	N	N
62608	Spectrophotometric Method, Pregnanetriol	B	2a	2	1	N	N
62609	Spectrophotometric, Uroporphyrin	B	2a	2	1	N	N
62610	St2 Assay	C	2b	3	2	N	N
62611	Stannous Chloride - Hydrazine, Phospholipids	B	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62612	Starch-Dye Bound Polymer, Amylase	B	2a	2	2	N	N
62613	Station, Pipetting And Diluting, For Clinical Use	B	2a	2	1	N	N
62614	Strip, Paper, Salicylate	B	2a	2	2	N	N
62615	Strip, Test Isoniazid	B	2a	2	U	N	N
62616	Sulfophosphovanillin, Colorimetry, Total Lipids	B	2a	2	1	N	N
62617	System, Breath Measurement	B	2a	2	1	N	N
62618	System, Imaging, Fluorescence	C	2b	3	3	N	N
62619	System, Test, Amino Acids, Free Carnitines And Acylcarnitines Tandem Mass Spectrometry	B	2a	2	2	N	N
62620	System, Test, Blood Glucose, Over The Counter	C	2b	3	2	N	N
62621	System, Test, Human Chorionic Gonadotropin	B	2a	2	2	N	N
62622	System, Test, Lipoprotein(A)	B	2a	2	1	N	N
62623	System, Test, Low Density, Lipoprotein	B	2a	2	1	N	N
62624	System, Test, Osteocalcin	B	2a	2	2	N	N
62625	System, Test, Oxalate	B	2a	2	1	N	N
62626	System, Test, Topiramate	B	2a	2	U	N	N
62627	System, Test, Urinary Methylmalonic Acid	B	2a	2	2	N	N
62628	System, Test, Vitamin D	B	2a	2	2	N	N
62629	System, Test, Biotinidase	B	2a	2	2	N	N
62630	System, Test, Breath Nitric Oxide	B	2a	2	2	N	N
62631	System, Test, Sodium, Enzymatic Method	B	2a	2	2	N	N
62632	System, Test, Total Antioxidant Status	B	2a	2	3	N	N
62633	Tanks, Developing, Tlc	A	1	1	1	N	N
62634	Test Reagents For Chloral Hydrate	B	2a	2	U	N	N
62635	Test Reagents For Ethyl Alcohol	B	2a	2	2	N	N
62636	Test Reagents For Methyl Alcohol	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62637	Test Reagents For Phenothiazine	B	2a	2	2	N	N
62638	Test Reagents For Sulphanimide Derivatives	B	2a	2	1	N	N
62639	Test Reagents, Zinc	B	2a	2	U	N	N
62640	Test System, For Drugs Of Abuse	B	2a	2	3	N	N
62641	Test System, Nicotine, Cotinine, Metabolites	B	2a	2	1	N	N
62642	Test, Albumin Cobalt Binding	B	2a	2	2	N	N
62643	Test, Amphetamine, Over The Counter	B	2a	2	2	N	N
62644	Test, Benzodiazepine, Over The Counter	B	2a	2	2	N	N
62645	Test, Breath Analysis, Volatile Organic Compounds	C	2b	3	F	N	N
62646	Test, Cannabinoid, Over The Counter	B	2a	2	2	N	N
62647	Test, Cholesterol, Total, Over The Counter	B	2a	2	1	N	N
62648	Test, Cocaine And Cocaine Metabolites, Over The Counter	B	2a	2	2	N	N
62649	Test, Creatinine, Over The Counter	B	2a	2	2	N	N
62650	Test, Cystatin C	B	2a	2	2	N	N
62651	Test, Follicle Stimulating Hormone (Fsh), Over The Counter	B	2a	2	1	N	N
62652	Test, Lactic Acid, Over The Counter	B	2a	2	1	N	N
62653	Test, Luteinizing Hormone (Lh), Over The Counter	B	2a	2	1	N	N
62654	Test, Methamphetamine, Over The Counter	B	2a	2	2	N	N
62655	Test, Morphine, Over The Counter	B	2a	2	2	N	N
62656	Test, Nitrite, Urinary, Non-Quantitative, Over The Counter	B	2a	2	1	N	N
62657	Test, Opiates, Over The Counter	B	2a	2	2	N	N
62658	Test, Triglycerides, Over The Counter	B	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62659	Test, Volatile Organic Compounds Breath Analysis	C	2b	3	U	N	N
62660	Test, Carbohydrate Deficient Transferrin	B	2a	2	1	N	N
62661	Test, Immunoassay, Biosensor, Hcg	B	2a	2	2	N	N
62662	Test, Natriuretic Peptide	C	2b	3	2	N	N
62663	Test, Natriuretic Peptide	C	2b	3	2	N	N
62664	Test, System, Potassium, Enzymatic Method	B	2a	2	2	N	N
62665	Tetrabromo-M-Cresolsulfonphthalein, Albumin	B	2a	2	2	N	N
62666	Tetrabromophenolphthalein, Albumin	B	2a	2	2	N	N
62667	Tetrahydrofolate, Enzymatic (U.V.), Formiminoglutamic Acid	B	2a	2	1	N	N
62668	Tetraphenyl Borate, Colorimetry, Potassium	B	2a	2	2	N	N
62669	Tetrazolium Int Dye-Diaphorase, Lactate Dehydrogenase	B	2a	2	2	N	N
62670	Theophylline Control Materials	B	2a	2	1	N	N
62671	Thermocycler, Generic	A	1	1	1	N	N
62672	Thin Layer Chromatography, Amphetamine	B	2a	2	2	N	N
62673	Thin Layer Chromatography, Barbiturate	B	2a	2	2	N	N
62674	Thin Layer Chromatography, Benzodiazepine	B	2a	2	2	N	N
62675	Thin Layer Chromatography, Benzoylcegonine	B	2a	2	2	N	N
62676	Thin Layer Chromatography, Cocaine	B	2a	2	2	N	N
62677	Thin Layer Chromatography, Codeine	B	2a	2	2	N	N
62678	Thin Layer Chromatography, Diphenylhydantoin	B	2a	2	2	N	N
62679	Thin Layer Chromatography, Ethosuximide	B	2a	2	2	N	N
62680	Thin Layer Chromatography, Metamphetamine	B	2a	2	2	N	N
62681	Thin Layer Chromatography, Methadone	B	2a	2	2	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62682	Thin Layer Chromatography, Morphine	B	2a	2	2	N	N
62683	Thin Layer Chromatography, Opiates	B	2a	2	2	N	N
62684	Thin Layer Chromatography, Phencyclidine	B	2a	2	U	N	N
62685	Thin Layer Chromatography, Phenobarbital	B	2a	2	2	N	N
62686	Thin Layer Chromatography, Primidone	B	2a	2	2	N	N
62687	Thin Layer Chromatography, Propoxyphene	B	2a	2	2	N	N
62688	Thin Layer Chromatography, Quinine	B	2a	2	1	N	N
62689	Thin Layer Chromatography, Salicylate	B	2a	2	2	N	N
62690	Thin Layer Chromatography, Theophylline	B	2a	2	2	N	N
62691	Thin Layer Chromatography, Tricyclic Antidepressant Drugs	B	2a	2	2	N	N
62692	Thymol Blue Monophosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62693	Thymolphthalein Monophosphate, Alkaline Phosphatase Or Isoenzymes	B	2a	2	2	N	N
62694	Timed Flow In Capillary, Plasma Viscometry	B	2a	2	U	N	N
62695	Timer, General Laboratory	U	U	U	1	N	N
62696	Titrimetric Permanganate And Bromophenol Blue, Calcium	B	2a	2	2	N	N
62697	Titrimetric Phenol Red, Carbon-Dioxide	B	2a	2	2	N	N
62698	Titrimetric With Edta And Indicator, Calcium	B	2a	2	2	N	N
62699	Titrimetric, Fatty Acids	B	2a	2	1	N	N
62700	Titrimetric, Magnesium	B	2a	2	1	N	N
62701	Tlc Chromatographic Separation Triglycerides	B	2a	2	1	N	N
62702	Tonometer (Calibration And Q.C. Of Blood-Gas Instruments), Clinical	B	2a	2	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62703	Tray, Blood Collection	B	2a	2	2	N	N
62704	Trinitrobenzene Sulfonate (Spectroscopic), Nitrogen (Amino-Nitrogen)	B	2a	2	1	N	N
62705	Tryptophan Measurement (Colorimetric), Globulin	B	2a	2	1	N	N
62706	Tubeless Analysis, Gastric Acidity	B	2a	2	1	N	N
62707	Tubes, Vacuum Sample, With Anticoagulant	B	2a	2	2	N	N
62708	Tubes, Vials, Systems, Serum Separators, Blood Collection	B	2a	2	2	N	N
62709	Turbidimetric Method, Globulin	B	2a	2	1	N	N
62710	Turbidimetric Method, Lipoproteins	B	2a	2	1	N	N
62711	Turbidimetric Method, Protein Or Albumin (Urinary, Non-Quant.)	B	2a	2	1	N	N
62712	Turbidimetric Method, Triglycerides	B	2a	2	1	N	N
62713	Turbidimetric, Total Protein	B	2a	2	2	N	N
62714	U.V. Light, Tlc	B	2a	2	1	N	N
62715	U.V. Method, Cpk Isoenzymes	C	2b	3	2	N	N
62716	U.V. Method, Galactose	B	2a	2	1	N	N
62717	U.V. Spectrometry, Carbamazepine	B	2a	2	2	N	N
62718	U.V. Spectrometry, Diphenylhydantoin	B	2a	2	2	N	N
62719	U.V. Spectrometry, Phenobarbital	B	2a	2	2	N	N
62720	U.V. Spectrometry, Primidone	B	2a	2	2	N	N
62721	U.V. Spectrometry, Theophylline	B	2a	2	2	N	N
62722	U.V. Spectrometry, Tricyclic Antidepressant Drugs	B	2a	2	2	N	N
62723	Unit, Drying	A	1	1	1	N	N
62724	Unit, Filter, Membrane	A	1	1	1	N	N

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862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES							
62725	Uranyl Acetate/Zinc Acetate, Sodium	B	2a	2	2	N	N
62726	Urease And Glutamic Dehydrogenase, Urea Nitrogen	B	2a	2	2	N	N
62727	Urease, Photometric, Urea Nitrogen	B	2a	2	2	N	N
62728	Uridine-5-Diphosphoglucose, Nad (U.V.), Alpha-D Galactose-1-Phosphate	B	2a	2	2	N	N
62729	Urinalysis Controls (Assayed And Unassayed)	B	2a	2	1	N	N
62730	Urinary Carbohydrate Analysis Kit	B	2a	2	1	N	N
62731	Urinary Homocystine (Nonquantitative) Test System	B	2a	2	2	N	N
62732	Vanillin Pyruvate, Alt/Sgpt	B	2a	2	1	N	N
62733	Vanillin Pyruvate, Ast/Sgot	B	2a	2	2	N	N
62734	Vapor Pressure, Osmolality Of Serum & Urine	B	2a	2	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64001	11-Dehydro Thromboxane B2 Kit, Urinary	B	2a	2	2	N	N
64002	Abnormal Hemoglobin Quantitation	B	2a	2	2	N	N
64003	Acid Hematin	A	1	1	2	N	N
64004	Acid Phosphatase, Cytochemical	B	2a	2	1	N	N
64005	Acid, Aniline, Fuchsin	A	1	1	1	N	N
64006	Acid, Fuchsin	A	1	1	1	N	N
64007	Acid, Hematein	A	1	1	1	N	N
64008	Acid, Osmic	A	1	1	1	N	N
64009	Acid, Periodic	A	1	1	1	N	N
64010	Acridine Orange	A	1	1	1	N	N
64011	Activated Partial Thromboplastin	B	2a	2	2	N	N
64012	Activated Whole Blood Clotting Time	B	2a	2	2	N	N
64013	Adenine Nucleotide Quantitation	B	2a	2	1	N	N
64014	Adhesive, Albumin-Based	B	2a	2	1	N	N
64015	Agent, Chelating For Decalcification	A	1	1	1	N	N
64016	Agent, Clearing	B	2a	2	1	N	N
64017	Aggregometer, Platelet, Photo-Optical Scanning	B	2a	2	2	N	N
64018	Aggregometer, Platelet, Thrombokinetogram	B	2a	2	2	N	N
64019	Aggregometer, Platelet	B	2a	2	2	N	N
64020	Alcian Blue	A	1	1	1	N	N
64021	Aldehyde Fuchsin	A	1	1	1	N	N
64022	Alizarin Red	A	1	1	1	N	N
64023	Alkaline Phosphatase	B	2a	2	1	N	N
64024	Ammoniacal Silver Hydroxide Silver Nitrate	A	1	1	1	N	N
64025	Analyzer, Chromosome, Automated	B	2a	2	2	N	N
64026	Analyzer, Heparin, Automated	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64027	Aniline	A	1	1	1	N	N
64028	Aniline Blue	A	1	1	1	N	N
64029	Antigen, Antiserum, Control, Antithrombin Iii	B	2a	2	2	N	N
64030	Antithrombin Iii Quantitation	B	2a	2	2	N	N
64031	Antithrombin Iii, Two Stage Clotting Time Assay	B	2a	2	2	N	N
64032	Apparatus, Automated Blood Cell Diluting	D	3	2	1	N	N
64033	Apparatus, Cell-Freezing And Reagents	B	2a	2	1	N	N
64034	Apparatus, Melting Point, Paraffin	B	2a	2	1	N	N
64035	Apparatus, Perfusion	A	1	1	1	N	N
64036	Apparatus, Roller	A	1	1	1	N	N
64037	Assay, 1,5-Anhydroglucitol (15ag)	B	2a	2	2	N	N
64038	Assay, Alpha-2-Antiplasmin	B	2a	2	2	N	N
64039	Assay, B Lymphocyte Marker	B	2a	2	2	N	N
64040	Assay, Bart'S, Hemoglobin	B	2a	2	2	N	N
64041	Assay, Carboxyhemoglobin	B	2a	2	2	N	N
64042	Assay, Erythrocytic Glucose-6-Phosphate Dehydrogenase	B	2a	2	2	N	N
64043	Assay, Erythropoietin	B	2a	2	2	N	N
64044	Assay, Fetal Hemoglobin	B	2a	2	2	N	N
64045	Assay, Glutathione Reductase	B	2a	2	2	N	N
64046	Assay, Glycosylated Hemoglobin	B	2a	2	2	N	N
64047	Assay, Heparin	B	2a	2	2	N	N
64048	Assay, Interleukin	B	2a	2	3	N	N
64049	Assay, Proliferation, In Vitro, T Lymphocyte	B	2a	2	2	N	N
64050	Assay, Sulfhemoglobin	B	2a	2	2	N	N
64051	Assay, T Lymphocyte Surface Marker	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64052	Atp Release (Luminescence)	B	2a	2	1	N	N
64053	Auramine O	A	1	1	1	N	N
64054	Automated Digital Image Manual Interpretation Microscope	B	2a	2	2	N	N
64055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	2	N	N
64056	Azan Counterstain	A	1	1	1	N	N
64057	Azocarmine B	A	1	1	1	N	N
64058	Azocarmine G	D	3	1	1	N	N
64059	Azure A	A	1	1	1	N	N
64060	Azure C	A	1	1	1	N	N
64061	Basic Fuchsin	A	1	1	1	N	N
64062	Bath, Flotation, Tissue	A	1	1	1	N	N
64063	Best'S Carmine	D	3	1	1	N	N
64064	Biebrich Scarlet	A	1	1	1	N	N
64065	Bismarck Brown Y	A	1	1	1	N	N
64066	Blender, Sputum	A	1	1	1	N	N
64067	Blood Establishment Computer Software, User Developed	B	2a	2	U	N	N
64068	Blood, Occult, Colorimetric, In Urine	B	2a	2	2	N	N
64069	Blood, Occult, Enzymatic Method, In Urine	B	2a	2	2	N	N
64070	Bothrops Atox Reagent	B	2a	2	2	N	N
64071	Bottle, Roller, Tissue Culture	A	1	1	1	N	N
64072	Boxes, View, Blood Grouping	A	1	1	1	N	N
64073	Brilliant Cresyl Blue	A	1	1	1	N	N
64074	Brilliant Green	A	1	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64075	Brilliant Yellow	A	1	1	1	N	N
64076	Calibrator For Cell Indices	B	2a	2	2	N	N
64077	Calibrator For Hemoglobin And Hematocrit Measurement	B	2a	2	2	N	N
64078	Calibrator For Platelet Counting	B	2a	2	2	N	N
64079	Calibrator For Red-Cell And White-Cell Counting	B	3	2	2	N	N
64080	Carbol Fuchsin	A	1	1	1	N	N
64081	Carbol Night Blue	A	1	1	1	N	N
64082	Carmine	A	1	1	1	N	N
64083	Cassettes, Tissue	A	1	1	1	N	N
64084	Cell Enzymes (Erythrocytic And Leukocytic)	B	2a	2	2	N	N
64085	Celloidin	D	3	1	1	N	N
64086	Cells, Animal And Human, Cultured	A	1	1	1	N	N
64087	Centrifuge, Blood-Bank For In Vitro Diagnostic Use	B	2a	2	1	N	N
64088	Centrifuge, Cell-Washing, Automated For Immuno-Hematology	D	3	3	2	N	N
64089	Centrifuge, Hematocrit	D	3	2	2	N	N
64090	Centrifuge, Microsedimentation	B	2a	2	1	N	N
64091	Chamber, Environmental For The Storage Of Platelet Concentrate	C	2b	3	2	N	N
64092	Chamber, Slide Culture	A	1	1	1	N	N
64093	Chlorazol Black E	A	1	1	1	N	N
64094	Colchicine	A	1	1	1	N	N
64095	Collodion	A	1	1	1	N	N
64096	Column, Adsorption, Low Density, Lipoprotein	D	3	3	3	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64097	Columns, Immunoabsorption In Extracorporeal Systems	C	2b	3	3	N	N
64098	Condensers, Microscope	A	1	1	1	N	N
64099	Congo Red	A	1	1	1	N	N
64100	Container, Embedding	B	2a	2	1	N	N
64101	Container, Empty, For Collection & Processing Of Blood & Blood Components	B	2a	2	2	N	N
64102	Container, Specimen Mailer And Storage, Non-Sterile	A	3	1	1	N	N
64103	Container, Specimen Mailer And Storage, Sterile	A	1	1	1	N	N
64104	Container, Specimen Mailer And Storage, Temperature Controlled, Non-Sterile	B	2a	2	1	N	N
64105	Container, Specimen Mailer And Storage, Temperature Controlled, Sterile	A	1	1	1	N	N
64106	Container, Specimen, Non-Sterile	A	1	1	1	N	N
64107	Container, Specimen, Sterile	B	2a	2	1	N	N
64108	Container, Specimen, Urine, Drugs Of Abuse, Over The Counter	A	1	1	1	N	N
64109	Control Material, Blood Circulating Epithelial Cancer Cell	B	2a	2	2	N	N
64110	Control Material, Her-2/Neu, Immunohistochemistry	B	2a	2	2	N	N
64111	Control, Cell Counter, Normal And Abnormal	B	2a	2	2	N	N
64112	Control, Fecal Occult Blood	B	2a	2	2	N	N
64113	Control, Hematocrit	B	2a	2	2	N	N
64114	Control, Hemoglobin	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64115	Control, Hemoglobin, Abnormal	B	2a	2	2	N	N
64116	Control, Plasma, Abnormal	B	2a	2	2	N	N
64117	Control, Platelet	B	2a	2	2	N	N
64118	Control, Red-Cell	B	2a	2	2	N	N
64119	Control, White-Cell	B	2a	2	2	N	N
64120	Cord Blood Processing System And Storage Container	B	2a	2	2	N	N
64121	Counter, Cell, Automated (Particle Counter)	B	2a	2	2	N	N
64122	Counter, Differential Cell	B	2a	2	2	N	N
64123	Counter, Urine Particle	B	2a	2	2	N	N
64124	Coverslips, Microscope Slide	A	1	1	1	N	N
64125	Cresyl Violet Acetate	A	1	1	1	N	N
64126	Cryogenic Cord Blood Storage Container	B	2a	2	2	N	N
64127	Crystal Violet For Histology	A	1	1	1	N	N
64128	Cyanomethemoglobin	B	2a	2	2	N	N
64129	Cyanomethemoglobin Reagent And Standard Solution	B	2a	2	2	N	N
64130	Cytocentrifuge	B	2a	2	1	N	N
64131	Darrow Red	A	1	1	1	N	N
64132	Detergent	A	1	1	1	N	N
64133	Device For Sealing Microsections	A	1	1	1	N	N
64134	Device, Accessory, Cooling Plate For Tissue Embedding Station	A	1	1	1	N	N
64135	Device, Automated Cell-Locating	B	2a	2	2	N	N
64136	Device, Automated Sedimentation Rate	B	2a	2	1	N	N
64137	Device, Bleeding Time	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64138	Device, Blood Mixing And Blood Weighing	B	2a	2	1	N	N
64139	Device, Blood Volume Measuring	B	2a	2	2	N	N
64140	Device, Decalcifier, Electrolytic	A	1	1	1	N	N
64141	Device, Heat-Sealing	D	3	1	1	N	N
64142	Device, Hematocrit Measuring	A	1	1	2	N	N
64143	Device, Warming. Blood And Plasma	B	2a	2	2	N	N
64144	Device,Ahf,Automated Cryoprecipitation	B	2a	2	U	N	N
64145	Device,Mixing And Weighing,Semi-Automated	B	2a	2	2	N	N
64146	Device,Preparation,Fibrin Sealant	C	2b	3	N	N	N
64147	Dialyzer Reprocessing System	B	2a	2	U	N	N
64148	Diastase	B	2a	2	1	N	N
64149	Diluent, Blood Cell	B	2a	2	1	N	N
64150	Dish, Tissue Culture	A	1	1	1	N	N
64151	Dispensers, Paraffin	A	1	1	1	N	N
64152	Dna-Probe, B And T Lymphocyte	B	2a	2	2	N	N
64153	Dna-Probe, Human Chromosome	B	2a	2	U	N	N
64154	Ecarin Clotting Time	C	2b	3	U	N	N
64155	Enzyme Linked Immunosorbent Assay, Thrombus Precursor Protein	B	2a	2	U	N	N
64156	Eosin B	A	1	1	1	N	N
64157	Eosin Y	A	1	1	1	N	N
64158	Erythrosin B	A	1	1	1	N	N
64159	Esterase	B	2a	2	1	N	N
64160	Ethyl Eosin	A	1	1	1	N	N
64161	Fast Green	A	1	1	1	N	N
64162	Fast Red Salt B	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
864 HEMATOLOGY AND PATHOLOGY DEVICES							
64163	Fibrin Monomer Paracoagulation	B	2a	2	2	N	N
64164	Fibrin Split Products	B	2a	2	2	N	N
64165	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control	B	2a	2	2	N	N
64166	Fibrinogen And Split Products, Antigen, Antiserum, Control	B	2a	2	2	N	N
64167	Fibrinogen And Split Products, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
64168	Fibrinogen And Split Products, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
64169	Fibrinogen And Split Products, Rhodamine, Antigen, Antiserum, Control	B	3	2	2	N	N
64170	Fibrinogen Determination Standards And Controls	B	3	2	2	N	N
64171	Fibrinogen Standard	B	3	2	2	N	N
64172	Fibrometer	B	3	2	2	N	N
64173	Filters, Cell Collection, Tissue Processing	A	3	1	1	N	N
64174	Fixative, Acid Containing	A	3	1	1	N	N
64175	Fixative, Alcohol Containing	A	3	1	1	N	N
64176	Fixative, Formalin-Containing	A	3	1	1	N	N
64177	Fixative, Metallic Containing	A	3	1	1	N	N
64178	Fixative, Richardson Glycol	A	3	1	1	N	N
64179	Flask, Tissue Culture	A	1	1	1	N	N
64180	Flow Cytometric Reagents And Accessories.	B	3	2	2	N	N
64181	Fluid, Bouin'S	A	3	1	1	N	N
64182	Fluid, Diluting, Manual Cell	A	3	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64183	Fluid, Diluting, Red-Cell	A	3	1	1	N	N
64184	Fluid, Diluting, White-Cell	A	3	1	1	N	N
64185	Fluorescence, Visual Observation (Qual., U.V.), Glutathione Reductase	B	3	2	2	N	N
64186	Formaldehyde (Formalin, Formol)	A	3	1	1	N	N
64187	Formalin, Neutral Buffered	D	3	1	1	N	N
64188	Formalin-Saline	A	3	1	1	N	N
64189	Formulations, Balanced Salt Solutions	A	3	1	1	N	N
64190	Formulations, Mercuric Chloride For Tissue	A	3	1	1	N	N
64191	Formulations, Paraffin, All	A	3	1	1	N	N
64192	Gelatin	A	3	1	1	N	N
64193	Gelatin For Specimen Adhesion	A	3	1	1	N	N
64194	Gelatin-Formalin	A	1	1	1	N	N
64195	Giemsa Stain	A	1	1	1	N	N
64196	Glenner'S Stain	A	1	1	1	N	N
64197	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Catalase Inhibition	B	2a	2	2	N	N
64198	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Electrophoresis	B	3	2	2	N	N
64199	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Methemoglobin Reduction	B	2a	2	2	N	N
64200	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Micromethod	B	2a	2	2	N	N
64201	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Quantitative	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64202	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Screening	B	2a	2	2	N	N
64203	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Spot	B	2a	2	2	N	N
64204	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), U.V. Kinetic	B	2a	2	2	N	N
64205	Glutaraldehyde	A	1	1	1	N	N
64206	Glutathione, Red-Cell	B	2a	2	2	N	N
64207	Gold Chloride	A	1	1	1	N	N
64208	Grinder, Tissue	A	1	1	1	N	N
64209	Guaic Reagent	A	1	1	2	N	N
64210	Hand-Tally, Differential	A	1	1	1	N	N
64211	Hematocrit, Tube, Rack, Sealer, Holder	B	2a	2	2	N	N
64212	Hematoxylin	A	1	1	1	N	N
64213	Hematoxylin Harris'S	A	1	1	1	N	N
64214	Hematoxylin Mayer'S	A	1	1	1	N	N
64215	Hematoxylin Weigert'S	A	1	1	1	N	N
64216	Hematoxylin, Acid, Phosphotungstic	A	1	1	1	N	N
64217	Hematoxylin, Chrome Alum	A	1	1	1	N	N
64218	Hematoxylin, Ehrlich'S	A	1	1	1	N	N
64219	Hematoxylin, Iron, Weigert'S	A	1	1	1	N	N
64220	Hemocytometer	B	2a	2	1	N	N
64221	Hemoglobin A2 Quantitation	B	2a	2	2	N	N
64222	Hemoglobin C (Abnormal Hemoglobin Variant)	B	2a	2	2	N	N
64223	Hemoglobin F Quantitation	B	2a	2	2	N	N
64224	Hemoglobin M	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64225	Hemoglobin S	B	2a	2	2	N	N
64226	Hemoglobin, Alkali Resistant	B	2a	2	2	N	N
64227	Hemoglobinometer	B	2a	2	2	N	N
64228	Heparin	B	2a	2	1	N	N
64229	Hyaluronidase	B	2a	2	1	N	N
64230	Immunohistochemical Reagent, Antibody (Monoclonal Or Polyclonal) To P63 Protein In Nucleus Of Prostatic Basal Cells	B	2a	2	1	N	N
64231	Immunohistochemistry Antibody Assay, C-Kit	C	2b	3	3	N	N
64232	Immunohistochemistry Antibody Assay, Estrogen Receptor	B	2a	2	2	N	N
64233	Immunohistochemistry Assay, Antibody, Epidermal Growth Factor Receptor	B	2a	2	3	N	N
64234	Immunohistochemistry Assay, Antibody, Progesterone Receptor	B	2a	2	2	N	N
64235	Immunohistochemistry Reagents And Kits	A	1	1	1	N	N
64236	Indigocarmine	A	1	1	1	N	N
64237	Infiltrator	A	1	1	1	N	N
64238	Instrument, Automated Platelet Counting	B	2a	2	2	N	N
64239	Instrument, Coagulation	C	2b	3	2	N	N
64240	Instrument, Coagulation, Automated	C	2b	3	2	N	N
64241	Instrument, Hematocrit, Automated	B	2a	2	2	N	N
64242	Iodine (Tincture)	A	1	1	1	N	N
64243	Iodine, Grams	A	1	1	1	N	N
64244	Iron Chloride-Weigert	A	1	1	1	N	N
64245	Iron Stains	A	1	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64246	Irradiation,Blood Indicators	A	1	1	U	N	N
64247	Irradiator, Blood To Prevent Graft Versus Host Disease	C	2b	3	U	N	N
64248	Isoenzymes, Electrophoretic, Glucose-6-Phosphate Dehydrogenase	B	2a	2	2	N	N
64249	Janus Green B	A	1	1	1	N	N
64250	Jenner Stain	A	1	1	1	N	N
64251	Kit, Assay, Estrogen Receptor	B	2a	2	3	N	N
64252	Kit, Assay, Progesterone Receptor	C	2b	3	3	N	N
64253	Kit, Cell Screening, Fetal	B	2a	2	U	N	N
64254	Kit, Culture, Chromosome	D	1	1	1	N	N
64255	Kit, Igg, Platelet Associated	D	2a	2	2	N	N
64256	Kit, Mycoplasma Detection	D	2a	2	1	N	N
64257	Kit, Quality Control For Blood Banking Reagents	D	2b	3	2	N	N
64258	Kit,Cord Blood Collection	D	2a	2	U	N	N
64259	Lamps, Microscope	D	1	1	1	N	N
64260	Lamps, Slide Warming	D	1	1	1	N	N
64261	Lectins And Protectins	D	2b	3	2	N	N
64262	Leuco-Patent Blue	A	1	1	1	N	N
64263	Light Green	A	1	1	1	N	N
64264	Light, Microscope	A	1	1	1	N	N
64265	Lipoprotein, Low Density, Removal	C	2b	3	3	N	N
64266	Luxol Fast Blue	A	1	1	1	N	N
64267	Lymphocyte Separation Medium	B	2a	2	1	N	N
64268	Malachite Green	A	1	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64269	Manual Blood Grouping And Antibody Test Systems	C	2b	3	2	N	N
64270	Martius Yellow	A	1	1	1	N	N
64271	Material, Quality Control, Semen Analysis	B	2a	2	2	N	N
64272	Media And Components, Mycoplasma Detection	A	1	1	1	N	N
64273	Media And Components, Synthetic Cell And Tissue Culture	A	1	1	1	N	N
64274	Media, Mounting, Oil Soluble	A	1	1	1	N	N
64275	Media, Mounting, Water Soluble	A	1	1	1	N	N
64276	Media, Mycoplasma Detection	B	2a	2	1	N	N
64277	Media, Potentiating For In Vitro Diagnostic Use	C	2b	3	2	N	N
64278	Melting Pot, Paraffin	B	2a	2	1	N	N
64279	Metanil Yellow	A	1	1	1	N	N
64280	Methenamine Silver	A	1	1	1	N	N
64281	Methyl Green	A	1	1	1	N	N
64282	Methyl Orange	A	1	1	1	N	N
64283	Methyl Violet 2b	A	1	1	1	N	N
64284	Methylene Blue Thiocyanate	A	1	1	1	N	N
64285	Methylene Blue, Tissue Stain	A	1	1	1	N	N
64286	Methylene Violet	A	1	1	1	N	N
64287	Micrometers, Microscope	A	1	1	1	N	N
64288	Microscope, Automated, Image Analysis, Operator Intervention	A	1	1	2	N	N
64289	Microscope, Fluorescence/U.V.	A	1	1	1	N	N
64290	Microscope, Inverted Stage, Tissue Culture	A	1	1	1	N	N
64291	Microscope, Phase Contrast	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
864 HEMATOLOGY AND PATHOLOGY DEVICES							
64292	Microscope,Automated,Image Analysis,Immunohistochemistry,Operator Intervention,Nuclear Intensity & Percent Positivity	B	2a	2	2	N	N
64293	Microtome, Accessories	A	1	1	1	N	N
64294	Microtome, Cryostat	A	1	1	1	N	N
64295	Microtome, Freezing Attachment	A	1	1	1	N	N
64296	Microtome, Rotary	A	1	1	1	N	N
64297	Microtome, Sliding	A	1	1	1	N	N
64298	Microtome, Ultra	A	1	1	1	N	N
64299	Mixture, Control, White-Cell And Red-Cell Indices	B	2a	2	2	N	N
64300	Mixture, Hematology Quality Control	B	2a	2	2	N	N
64301	Molecular Adsorbent Recirculating System (Mars)	C	2b	3	U	N	Y
64302	Mounting Media	A	1	1	1	N	N
64303	Mucicarmin	A	1	1	1	N	N
64304	Muller'S Colloidal Iron	A	1	1	1	N	N
64305	Nadp Reduction (U.V.), Glucose-6-Phosphate Dehydrogenase	B	2a	2	2	N	N
64306	Neuramininase (Sialidase)	B	2a	2	1	N	N
64307	Neutral Red	A	1	1	1	N	N
64308	Nigrosin	A	1	1	1	N	N
64309	Nile Blue	A	1	1	1	N	N
64310	Nuclear Fast Red	A	1	1	1	N	N
64311	Oil Red O	A	1	1	1	N	N
64312	Oil, Clearing	A	1	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64313	Orange G	A	1	1	1	N	N
64314	Orange li	A	1	1	1	N	N
64315	Orcein	A	1	1	1	N	N
64316	Osmium Tetroxide	A	1	1	1	N	N
64317	Osmotic Fragility Testing	B	2a	2	1	N	N
64318	Ovens, Paraffin	B	2a	2	1	N	N
64319	Oximeter To Measure Hemoglobin	B	2a	2	2	N	N
64320	Oxyhemoglobin	B	2a	2	2	N	N
64321	Papain	B	2a	2	1	N	N
64322	Paraformaldehyde	A	1	1	1	N	N
64323	Peroxidase Anti-Peroxidase Immunohistochemical Stain	A	1	1	1	N	N
64324	Ph Buffer	A	1	1	1	N	N
64325	Phloxine B	A	1	1	1	N	N
64326	Phytohemagglutinin M	A	1	1	1	N	N
64327	Picro Methyl Blue	A	1	1	1	N	N
64328	Pipette, Diluting	A	1	1	1	N	N
64329	Pipette, Pasteur	B	2a	2	1	N	N
64330	Pipette, Quantitative, Hematology	B	2a	2	1	N	N
64331	Pipette, Sahli	A	1	1	1	N	N
64332	Plasma, Coagulation Control	B	2a	2	2	N	N
64333	Plasma, Coagulation Factor Deficient	B	2a	2	2	N	N
64334	Plasma, Control, Normal	B	2a	2	2	N	N
64335	Plasma, Fibrinogen Control	B	2a	2	2	N	N
64336	Platelet And Plasma Separator For Bone Graft Handling	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64337	Platelet Counting, Manual	A	1	1	1	N	N
64338	Platelet Factor 4 Radioimmunoassay	B	2a	2	2	N	N
64339	Platelets, Photochemical Treatment System	C	2b	3	3	N	N
64340	Polyethylene Glycol (Carbowax)	A	1	1	1	N	N
64341	Polyethylene Glycol Preservative	A	1	1	1	N	N
64342	Potassium Periodate	A	1	1	1	N	N
64343	Preservative, Cytological	A	1	1	1	N	N
64344	Processor, Cervical Cytology Slide, Automated	C	2b	3	3	N	N
64345	Processor, Tissue, Automated	A	1	1	1	N	N
64346	Products, Red-Cell Lysing Products	B	2a	2	1	N	N
64347	Progenitor Cell Enumeration	B	2a	2	2	N	N
64348	Prostrate Cancer Genes Nucleic Acid Amplification Test System	C	2b	3	3	N	N
64349	Protamine Sulphate	B	2a	2	2	N	N
64350	Protargol S	A	1	1	1	N	N
64351	Prothrombin Fragment 1.2	B	2a	2	2	N	N
64352	Prothrombin-Proconvertin And Thrombotest	B	2a	2	2	N	N
64353	Pyronin	A	1	1	1	N	N
64354	Reader, Cervical Cytology Slide, Automated	C	2b	3	3	N	N
64355	Reagent & Control, Partial Thromboplastin Time	C	2b	3	2	N	N
64356	Reagent, General Purpose	A	1	1	1	N	N
64357	Reagent, Occult Blood	B	2a	2	2	N	N
64358	Reagent, Platelet Aggregation	B	2a	2	2	N	N
64359	Reagent, Russel Viper Venom	B	2a	2	1	N	N
64360	Reagent, Schiff	A	1	1	1	N	N
64361	Reagent, Thromboplastin And Control	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64362	Reagents,Specific,Analyte	B	2a	2	1	N	N
64363	Red-Cell Count By Photometry	B	2a	2	2	N	N
64364	Red-Cell Indices	B	2a	2	2	N	N
64365	Red-Cell Indices, Calculated	B	2a	2	2	N	N
64366	Red-Cell Indices, Measured	B	2a	2	2	N	N
64367	Red-Violet Lb	A	1	1	1	N	N
64368	Refrigerator, Freezer, Blood Storage	B	2a	2	2	N	N
64369	Research Use Only/Hematology Devices	B	2a	2	U	N	N
64370	Research Use Only/Pathology	U	U	U	U	N	N
64371	Resorcin Fuchsin	A	1	1	1	N	N
64372	Romanowsky Stains	A	1	1	1	N	N
64373	Rose Bengal	A	1	1	1	N	N
64374	Safranin	A	1	1	1	N	N
64375	Self-Contained Blood Grouping	C	2b	3	2	N	N
64376	Separator For Therapeutic Purposes, Membrane Automated Blood Cell/Plasma	C	2b	3	3	N	N
64377	Separator, Automated, Blood Cell And Plasma, Therapeutic	C	2b	3	U	N	N
64378	Separator, Automated, Blood Cell, Diagnostic	B	2a	2	2	N	N
64379	Separator,Semi-Automated,Blood Component	B	2a	2	1	N	N
64380	Sera, Animal And Human	A	1	1	1	N	N
64381	Set, Transfer (Blood/Plasma)	B	2a	2	2	N	N
64382	Sieves, Tissue	A	1	1	1	N	N
64383	Silver Nitrate	A	1	1	1	N	N
64384	Sirius Red	A	1	1	1	N	N
64385	Slide Stainer, Automated	B	2a	2	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64386	Slide Stainer, Contact Type	B	2a	2	1	N	N
64387	Slide Stainer, Immersion Type	B	2a	2	1	N	N
64388	Slides, Microscope	A	1	1	1	N	N
64389	Sodium Periodate	A	1	1	1	N	N
64390	Software, Blood Bank, Stand Alone Products	B	2a	2	2	N	N
64391	Software, Management, Microplate Assay	B	2a	2	U	N	N
64392	Solubility, Hemoglobin, Abnormal	B	2a	2	2	N	N
64393	Solution, Carnoy'S	A	1	1	1	N	N
64394	Solution, Clarke'S	A	1	1	1	N	N
64395	Solution, Copper Sulfate For Specific Gravity Determinations	A	1	1	1	N	N
64396	Solution, Decalcifier, Acid Containing	A	1	1	1	N	N
64397	Solution, Decalcifier, Electrolytic	A	1	1	1	N	N
64398	Solution, Fontanna Silver	A	1	1	1	N	N
64399	Solution, Formalin Ammonium Bromide	A	1	1	1	N	N
64400	Solution, Formalin-Alcohol-Acetic Acid	A	1	1	1	N	N
64401	Solution, Formalin-Sodium Acetate	A	1	1	1	N	N
64402	Solution, Formol Calcium	A	1	1	1	N	N
64403	Solution, Gugol Blue	A	1	1	1	N	N
64404	Solution, Helly	A	1	1	1	N	N
64405	Solution, Isotonic	A	1	1	1	N	N
64406	Solution, Lugol'S	A	1	1	1	N	N
64407	Solution, Newcomer'S	A	1	1	1	N	N
64408	Solution, Orth'S	A	1	1	1	N	N
64409	Solution, Silver Carbonate	A	1	1	1	N	N
64410	Solution, Stabilized Enzyme	A	1	1	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64411	Solution, Zenker'S	A	1	1	1	N	N
64412	Somatic Gene Mutation Detection System	C	2b	3	3	N	N
64413	Sorter, Cell	B	2a	2	U	N	N
64414	Specimen/Tissue, Identification Orientation	B	2a	2	1	N	N
64415	Spinner System, Cell Culture	A	1	1	1	N	N
64416	Spinner, Flask	A	1	1	1	N	N
64417	Spinner, Slide, Automated	B	2a	2	1	N	N
64418	Sprays, Synthetic, Smear	A	1	1	1	N	N
64419	Stages, Microscope	A	1	1	1	N	N
64420	Stain, Fetal Hemoglobin	B	2a	2	2	N	N
64421	Stain, Papanicolau	A	1	1	1	N	N
64422	Stain, Ponceau	A	1	1	1	N	N
64423	Stain, Reticulocyte	A	1	1	1	N	N
64424	Stain, Trichrome, Mallory'S	A	1	1	1	N	N
64425	Stainer, Tissue, Automated	B	2a	2	1	N	N
64426	Stains, Chemical Solution	A	1	1	1	N	N
64427	Stains, Dye Powder	A	1	1	1	N	N
64428	Stains, Dye Solution	A	1	1	1	N	N
64429	Stains, Heinz Body	A	1	1	1	N	N
64430	Stains, Hematology	B	2a	2	1	N	N
64431	Stains, Microbiologic	A	1	1	1	N	N
64432	Standards And Controls, Hemoglobin, Normal And Abnormal	B	2a	2	2	N	N
64433	Streptolysin O	B	2a	2	1	N	N
64434	Strip, Test, Reagent, Residuals For Dialysate	B	2a	2	U	N	N
64435	Study, Platelet Adhesive	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64436	Substance, Blood Grouping Of Non-Human Origin For In Vitro Diagnostic Use	C	2b	3	2	N	N
64437	Sudan Black B	A	1	1	1	N	N
64438	Sudan Iii	A	1	1	1	N	N
64439	Sudan Iv	A	1	1	1	N	N
64440	Supplies, Blood-Bank	B	2a	2	1	N	N
64441	Syrup, Gum, Apathy'S	A	1	1	1	N	N
64442	System, Analysis, Electrophoretic Hemoglobin	B	2a	2	2	N	N
64443	System, Automated Platelet Aggregation	B	2a	2	2	N	N
64444	System, Blood Collection, Vacuum-Assisted, Automated	B	2a	2	1	N	N
64445	System, Blood Collection, Vacuum-Assisted, Manual	B	2a	2	1	N	N
64446	System, Fibrinogen Determination	B	2a	2	2	N	N
64447	System, Hemoglobin, Automated	B	2a	2	2	N	N
64448	System, Multipurpose For In Vitro Coagulation Studies	B	2a	2	2	N	N
64450	System, Processing For Frozen Blood	A	1	1	2	N	N
64451	System, Suspension, Cell Culture	B	2a	2	1	N	N
64452	System, Test, Automated Blood Grouping And Antibody	C	2b	3	2	N	N
64453	System, Test, Combs, Automated	C	2b	3	2	N	N
64454	System, Concentration, Hematopoietic Stem Cell	D	3	4	3	N	N
64455	System, Detection, Bacterial, For Platelet Transfusion Products	C	2b	3	U	N	N
64456	System, Separation, Hematopoietic Stem Cell	D	3	4	3	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64457	System,Test,(Ihc),Tumor Marker,Monitoring,Bladder Cancer	C	2b	3	2	N	N
64458	Table, Slide Warming	A	1	1	1	N	N
64459	Tablet, Resazurin	A	1	1	1	N	N
64460	Test 5, 10-Methylenetetrahydrofolate Reductase Mutations, Genomic Dna Pcr	B	2a	2	2	N	N
64461	Test, Ecarin Clotting Time (Ect)	B	2a	2	U	N	N
64462	Test, Erythrocyte Sedimentation Rate	B	2a	2	1	N	N
64463	Test, Euglobulin Lysis	B	2a	2	2	N	N
64464	Test, Factor Ii G20210a Mutations, Genomic Dna Pcr	C	2b	3	2	N	N
64465	Test, Factor V Leiden Mutations, Genomic Dna Pcr	C	2b	3	2	N	N
64466	Test, Fibrinogen	B	2a	2	2	N	N
64467	Test, Fluorescence In Situ Hybridization (Fish), For Bladder Cancer Detection And Monitoring For Recurrence	C	2b	3	3	N	N
64468	Test, Glycosylated Hemoglobin, Over The Counter	B	2a	2	2	N	N
64469	Test, Heparin Neutralization	B	2a	2	2	N	N
64470	Test, Leukocyte Alkaline Phosphatase	B	2a	2	1	N	N
64471	Test, Leukocyte Peroxidase	B	2a	2	1	N	N
64472	Test, Leukocyte Typing	B	2a	2	1	N	N
64473	Test, Occult Blood, Over The Counter	B	2a	2	2	N	N
64474	Test, Prothrombin Consumption	B	2a	2	2	N	N
64475	Test, Qualitative And Quantitative Factor Deficiency	B	2a	2	2	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64476	Test, Screening, For D Positive Fetal Rbc'S	C	2b	3	2	N	N
64477	Test, Sickle Cell	B	2a	2	2	N	N
64478	Test, Thrombin Time	B	2a	2	2	N	N
64479	Test, Thromboplastin Generation	B	2a	2	1	N	N
64480	Test, Time, Partial Thromboplastin	C	2b	3	2	N	N
64481	Test, Time, Prothrombin	C	2b	3	2	N	N
64482	Test, Urine Leukocyte	B	2a	2	1	N	N
64483	Test,Qualitative,For Hla,Non-Diagnostic	B	2a	2	U	N	N
64484	Test,Quantitative,For Hla,Non-Diagnostic	C	2b	3	N	N	N
64485	Test,Residual,Wbc In Leukoreduced Blood	B	2a	2	2	N	N
64486	Thionin	A	1	1	1	N	N
64487	Thrombin	B	2a	2	2	N	N
64488	Timer, Clot, Automated	C	2b	3	2	N	N
64489	Timer, Coagulation	C	2b	3	2	N	N
64490	Tissue Culture, Accessories, Dental	A	1	1	1	N	N
64491	Titan Yellow	A	1	1	1	N	N
64492	Toluidine Blue	A	1	1	1	N	N
64493	Tray, Leukocyte Typing	C	2b	3	U	N	N
64494	Trinucleotide Repeat Disorder Dna Test	B	2a	2	U	N	N
64495	Trypan Blue	A	1	2	1	N	N
64496	Trypsin	B	2a	2	1	N	N
64497	Tube, Collection, Capillary Blood	B	2a	2	1	N	N
64498	Tube, Sedimentation Rate	A	1	1	1	N	N
64499	Tube, Tissue Culture	B	2a	2	1	N	N
64500	Urine Collection Kit (Excludes Hiv Testing)	A	1	1	1	N	N
64501	Urine Transport Kit (Excludes Hiv Testing)	A	1	1	1	N	N

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864 HEMATOLOGY AND PATHOLOGY DEVICES							
64502	Van Gieson'S Picro-Fuchsin	A	1	1	1	N	N
64503	Van Gieson'S Stain	A	1	1	1	N	N
64504	Vials,Challenge,Endotoxin	B	2a	2	U	N	N
64505	Visual, Semi-Quant. (Colorimetric), Glucose-6-Phosphate Dehydrogenase	B	2a	2	2	N	N
64506	Vitamin K Epoxide Reductase Complex Subunit One (Vkorc1) Genotyping System	B	2a	2	2	N	N
64507	Warmer, Blood, Electromagnetic Radiation	C	2b	3	3	N	N
64508	Warmer, Blood, Non-Electromagnetic Radiation	C	2b	3	2	N	N
64509	Whole Blood Hemoglobin Determination	B	2a	2	2	N	N
64510	Wright'S Stain	A	1	1	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66001	2009 H1n1 Influenza Virus (Swine Origin), Nucleic Acid Or Antigen, Detection And Identification	C	2b	3	2	N	N
66003	Albumin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66004	Albumin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66005	Albumin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66006	Alpha 2, 2n-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66007	Alpha-1 Microglobulin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66008	Alpha-1-Acid-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66009	Alpha-1-Antichymotrypsin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66010	Alpha-1-Antitrypsin Kit, Qualitative Phenotype	B	2a	2	2	N	N
66011	Alpha-1-Antitrypsin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66012	Alpha-1-Antitrypsin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66013	Alpha-1-Antitrypsin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66014	Alpha-1-B-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66015	Alpha-1-Lipoprotein, Antigen, Antiserum, Control	B	2a	2	2	N	N
66016	Alpha-1-T-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66017	Alpha-2-Ap-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66018	Alpha-2-Glycoproteins, Antigen, Antiserum, Control	B	2a	2	1	N	N
66019	Alpha-2-Hs-Glycoprotein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66020	Alpha-2-Macroglobulin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66021	Alpha-2-Macroglobulin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66022	Alpha-2-Macroglobulin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66023	Alpha-Globulin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66024	Anaerobic Box Glove	B	2a	2	1	N	N
66025	Antibodies, Anti-Actin, Anti-Smooth Muscle	B	2a	2	2	N	N
66026	Antibodies, Anti-Cyclic Citrullinated Peptide (Ccp)	B	2a	2	2	N	N
66027	Antibodies, Gliadin	B	2a	2	2	N	N
66028	Antibodies, Outer-Membrane Proteins	B	2a	2	2	N	N
66029	Antibodies, Saccharomyces Cerevisiae (S.Cerevisiae)	B	2a	2	2	N	N
66030	Antibody Igm, If, Epstein-Barr Virus	C	2b	3	1	N	N
66031	Antibody Igm, If, Cytomegalovirus Virus	C	2b	3	2	N	N
66032	Antibody To Htlv-1, Elisa	C	2b	3	3	N	Y
66032	Antibody To Htlv-1, Elisa	D	3	3	3	N	Y
66033	Antibody, Monoclonal Blocking, Hiv-1	C	2b	3	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66034	Antideoxyribonuclease, Streptococcus Spp.	B	2a	2	1	N	N
66035	Anti-Dna Antibody (Enzyme-Labeled), Antigen, Control	B	2a	2	2	N	N
66036	Anti-Dna Antibody, Antigen And Control	B	2a	2	2	N	N
66037	Anti-Dna Indirect Immunofluorescent Solid Phase	B	2a	2	2	N	N
66038	Antigen(Complexed),Prostate Specific,(Cpsa)	C	2b	3	3	N	N
66039	Antigen, Agglutinating, Echinococcus Spp.	B	2a	2	1	N	N
66040	Antigen, B. Parapertussis	B	2a	2	1	N	N
66041	Antigen, B. Pertussis	B	2a	2	1	N	N
66042	Antigen, Bentonite Flocculation, Trichinella Spiralis	B	2a	2	1	N	N
66043	Antigen, Blastomyces Dermatitidis, Other	B	2a	2	2	N	N
66044	Antigen, C. Difficile	C	2b	3	1	N	N
66045	Antigen, Cancer 549	C	2b	3	3	N	N
66046	Antigen, Cartilage Oligomeric Matrix Protein (Comp)	B	2a	2	2	N	N
66047	Antigen, Cf (Including Cf Control), Cytomegalovirus	C	2b	3	2	N	N
66048	Antigen, Cf (Including Cf Control), Epstein-Barr Virus	C	2b	3	1	N	N
66049	Antigen, Cf (Including Cf Control), Herpesvirus Hominis 1,2	C	2b	3	2	N	N
66050	Antigen, Cf (Including Cf Control), Mumps Virus	B	2a	2	1	N	N
66051	Antigen, Cf (Including Cf Control), Rubella	C	2b	3	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66052	Antigen, Cf (Including Cf Controls), Respiratory Syncytial Virus	B	2a	2	1	N	N
66053	Antigen, Cf And/Or Id, Coccidioides Immitis	B	2a	2	2	N	N
66054	Antigen, Cf, (Including Cf Control), Rubeola	B	2a	2	1	N	N
66055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	2	N	N
66056	Antigen, Cf, Aspergillus Spp.	B	2a	2	1	N	N
66057	Antigen, Cf, B. Dermatitidis	B	2a	2	2	N	N
66058	Antigen, Cf, Lymphocytic Choriomeningitis Virus	D	3	2	1	N	N
66059	Antigen, Cf, Psittacosis (Chlamydia Group)	C	2b	3	1	N	N
66060	Antigen, Cf, Q Fever	B	2a	2	1	N	N
66061	Antigen, Cf, Spotted Fever Group	B	2a	2	1	N	N
66062	Antigen, Cf, T. Cruzi	B	2a	2	1	N	N
66063	Antigen, Cf, Typhus Fever Group	D	3	2	1	N	N
66064	Antigen, Ebv, Capsid	C	2b	3	1	N	N
66065	Antigen, Elisa, Cryptococcus	C	2b	3	2	N	N
66066	Antigen, Enzyme Linked Immunoabsorbent Assay, Neisseria Gonorrhoeae	C	2b	3	2	N	N
66067	Antigen, Erysipelothrix Rhusiopathiae	B	2a	2	1	N	N
66068	Antigen, Fluorescent Antibody Test, Schistosoma Mansoni	B	2a	2	1	N	N
66069	Antigen, Galactomannan, Aspergillus Spp.	B	2a	2	1	N	N
66070	Antigen, Ha (Including Ha Control), Mumps Virus	B	2a	2	1	N	N
66071	Antigen, Ha (Including Ha Control), Rubella	C	2b	3	2	N	N
66072	Antigen, Ha (Including Ha Control), Rubeola	B	2a	2	1	N	N
66073	Antigen, Id, Candida Albicans	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66074	Antigen, Id, Ha, Cep, Entamoeba Histolytica & Rel. Spp.	B	2a	2	2	N	N
66075	Antigen, Iha, Cytomegalovirus	C	2b	3	2	N	N
66076	Antigen, Iha, T. Cruzi	B	2a	2	1	N	N
66077	Antigen, Indirect Fluorescent Antibody Test, Echinococcus Granulosus	B	2a	2	1	N	N
66078	Antigen, Inflammatory Response Marker, Sepsis	B	2a	2	2	N	N
66079	Antigen, Invasive Fungal Pathogens	B	3	2	2	N	N
66080	Antigen, Latex Agglutination, Coccidioides Immitis	B	2a	2	2	N	N
66081	Antigen, Latex Agglutination, Entamoeba Histolytica & Rel. Spp.	B	2a	2	2	N	N
66082	Antigen, Latex Agglutination, T. Cruzi	B	2a	2	1	N	N
66083	Antigen, Latex Agglutination, Trichinella Spiralis	B	2a	2	1	N	N
66084	Antigen, Positive Control, Cryptococcus Neoformans	C	2b	3	2	N	N
66085	Antigen, Rubella, Other	D	3	3	2	N	N
66086	Antigen, Treponema Pallidum For Fta-Abs Test	C	2b	3	2	N	N
66087	Antigens (Febrile), Agglutination, Brucella Spp.	B	2a	2	2	N	N
66088	Antigens, All Groups, Salmonella Spp.	D	3	2	2	N	N
66089	Antigens, All Groups, Shigella Spp.	D	3	2	2	N	N
66090	Antigens, All Groups, Streptococcus Spp.	C	2b	3	1	N	N
66091	Antigens, All Types, Escherichia Coli	B	2a	2	1	N	N
66092	Antigens, All, Leptospira Spp.	B	2a	2	2	N	N
66093	Antigens, Cf (Including Cf Control), Adenovirus 1-33	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66094	Antigens, Cf (Including Cf Control), Coxsackievirus A 1-24, B 1-6	B	2a	2	1	N	N
66095	Antigens, Cf (Including Cf Control), Echovirus 1-34	B	2a	2	1	N	N
66096	Antigens, Cf (Including Cf Control), Equine Encephalitis Virus, Eee, Wee	D	3	2	1	N	N
66097	Antigens, Cf (Including Cf Control), Influenza Virus A, B, C	B	2a	2	1	N	N
66098	Antigens, Cf (Including Cf Control), Parainfluenza Virus 1-4	B	2a	2	1	N	N
66099	Antigens, Cf (Including Cf Control), Poliovirus 1-3	B	2a	2	1	N	N
66100	Antigens, Cf (Including Cf Control), Reovirus 1-3	B	2a	2	1	N	N
66101	Antigens, Cf, All, Mycoplasma Spp.	B	2a	2	1	N	N
66102	Antigens, Cf, Toxoplasma Gondii	C	3	3	2	N	N
66103	Antigens, Febrile (Weil-Felix), All Groups	B	2a	2	1	N	N
66104	Antigens, Febrile, Slide And Tube, All Groups, Salmonella Spp.	B	2a	2	2	N	N
66105	Antigens, Ha (Including Ha Control), Adenovirus 1-33	B	2a	2	1	N	N
66106	Antigens, Ha (Including Ha Control), Influenza Virus A, B, C	B	2a	2	1	N	N
66107	Antigens, Ha (Including Ha Control), Parainfluenza Virus 1-4	B	2a	2	1	N	N
66108	Antigens, Ha (Including Ha Control), Reovirus 1-3	B	2a	2	1	N	N
66109	Antigens, Ha, Echovirus 1-34	B	2a	2	1	N	N
66110	Antigens, Ha, Treponema Pallidum	C	2b	3	2	N	N
66111	Antigens, Histoplasma Capsulatum, All	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66112	Antigens, If, Toxoplasma Gondii	C	2b	3	2	N	N
66113	Antigens, Iha, Toxoplasma Gondii	C	2b	3	2	N	N
66114	Antigens, Indirect Hemagglutination (Iha) Herpes Simplex Virus	C	2b	3	2	N	N
66115	Antigens, Nontreponemal, All	C	2b	3	2	N	N
66116	Antigens, Slide And Tube, All Types, Listeria Monocytogenes	C	2b	3	1	N	N
66117	Antigens, Slide And Tube, Francisella Tularensis	B	2a	2	2	N	N
66002	Anti-Glutamate Receptor (Type Nmda) Ifa	B	2a	2	2	N	N
66118	Anti-Human Globulin, Fta-Abs Test	C	2b	3	2	N	N
66119	Anti-Jcv Antibody Detection Assay	C	2b	3	2	N	N
66120	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control	B	2a	2	2	N	N
66121	Anti-Mutated Citrullinated Vimentin Igg	B	2a	2	2	N	N
66122	Antinuclear Antibody (Enzyme-Labeled), Antigen, Controls	B	2a	2	2	N	N
66123	Antinuclear Antibody, Antigen, Control	B	2a	2	2	N	N
66124	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control	B	2a	2	2	N	N
66125	Antiparietal Antibody, Indirect Immunofluorescent, Antigen, Control	B	2a	2	2	N	N
66126	Anti-Ribosomal P Antibodies	B	2a	2	2	N	N
66127	Anti-Rnp Antibody, Antigen And Control	B	2a	2	2	N	N
66128	Antisera, Acinetobacter Calcoaceticus, All Varieties	B	2a	2	1	N	N
66129	Antisera, Agglutinating, B. Parapertussis	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66130	Antisera, Agglutinating, B. Pertussis, All	B	2a	2	1	N	N
66131	Antisera, All Fluorescent, Leptospira Spp.	B	2a	2	2	N	N
66132	Antisera, All Groups, N. Meningitidis	C	2b	3	2	N	N
66133	Antisera, All Groups, Salmonella Spp.	B	2a	2	2	N	N
66134	Antisera, All Groups, Streptococcus Spp.	C	2b	3	1	N	N
66135	Antisera, All Leptospira Spp.	B	2a	2	2	N	N
66136	Antisera, All Mycoplasma Spp.	B	2a	2	1	N	N
66137	Antisera, All Types, Escherichia Coli	B	2a	2	1	N	N
66138	Antisera, All Types, H. Influenza	B	2a	2	2	N	N
66139	Antisera, All Types, Klebsiella Spp.	B	2a	2	1	N	N
66140	Antisera, All Types, Listeria Monocytogenes	D	3	3	1	N	N
66141	Antisera, All Types, Shigella Spp.	B	2a	2	2	N	N
66142	Antisera, All Types, Streptococcus Pneumoniae	B	2a	2	1	N	N
66143	Antisera, All, Serratia Marcesans	B	2a	2	1	N	N
66144	Antisera, Arizona Spp., All	B	2a	2	1	N	N
66145	Antisera, Bethesda - Ballerup Polyvalent, Citrobacter Spp.	B	2a	2	1	N	N
66146	Antisera, C. Acnes	B	2a	2	1	N	N
66147	Antisera, C. Acnes (553, 605)	B	2a	2	1	N	N
66148	Antisera, Cf, Adenovirus 1-33	B	2a	2	1	N	N
66149	Antisera, Cf, Coxsackievirus A 1-24, B 1-6	B	2a	2	1	N	N
66150	Antisera, Cf, Echovirus 1-34	B	2a	2	1	N	N
66151	Antisera, Cf, Equine Encephalitis Virus, Eee, Wee	B	2a	2	1	N	N
66152	Antisera, Cf, Herpesvirus Hominis 1,2	C	2b	3	2	N	N
66153	Antisera, Cf, Influenza Virus A, B, C	B	2a	2	1	N	N
66154	Antisera, Cf, Parainfluenza Virus 1-4	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66155	Antisera, Cf, Poliovirus 1-3	B	2a	2	1	N	N
66156	Antisera, Cf, Reovirus 1-3	B	2a	2	1	N	N
66157	Antisera, Cf, Rubella	C	2b	3	2	N	N
66158	Antisera, Conjugated Fluorescent, Cytomegalovirus	C	2b	3	2	N	N
66159	Antisera, Control For Nontreponemal Tests	C	2b	3	2	N	N
66160	Antisera, Fluorescent Antibody For Fta-Abs Test	C	2b	3	2	N	N
66161	Antisera, Fluorescent, Adenovirus 1-33	B	2a	2	1	N	N
66162	Antisera, Fluorescent, All Globulins, Proteus Spp.	B	2a	2	1	N	N
66163	Antisera, Fluorescent, All Globulins, Salmonella Spp.	B	2a	2	2	N	N
66164	Antisera, Fluorescent, All Globulins, Shigella Spp.	B	2a	2	2	N	N
66165	Antisera, Fluorescent, All Groups, N. Meningitidis	C	2b	3	2	N	N
66166	Antisera, Fluorescent, All Groups, Streptococcus Spp.	C	2b	3	1	N	N
66167	Antisera, Fluorescent, All Types, Escherichia Coli	B	2a	2	1	N	N
66168	Antisera, Fluorescent, All Types, Hemophilus Spp.	B	3	2	2	N	N
66169	Antisera, Fluorescent, All Types, Klebsiella Spp.	B	3	2	1	N	N
66170	Antisera, Fluorescent, All Types, Listeria Monocytogenes	C	3	3	1	N	N
66171	Antisera, Fluorescent, All Types, Staphylococcus Spp.	B	3	2	1	N	N
66172	Antisera, Fluorescent, All Types, Streptococcus Pneumoniae	C	3	3	1	N	N
66173	Antisera, Fluorescent, All, Mycoplasma Spp.	B	3	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66174	Antisera, Fluorescent, B. Parapertussis	B	3	2	1	N	N
66175	Antisera, Fluorescent, B. Pertussis	B	3	2	1	N	N
66176	Antisera, Fluorescent, Brucella Spp.	B	3	2	2	N	N
66177	Antisera, Fluorescent, Chlamydia Spp.	C	3	3	1	N	N
66178	Antisera, Fluorescent, Coxsackievirus A 1-24, B 1-6	B	2a	2	1	N	N
66179	Antisera, Fluorescent, Cryptococcus Neoformans	C	3	3	2	N	N
66180	Antisera, Fluorescent, Echovirus 1-34	B	3	2	1	N	N
66181	Antisera, Fluorescent, Herpesvirus Hominis 1,2	C	3	3	2	N	N
66182	Antisera, Fluorescent, Histoplasma Capsulatum	B	3	2	2	N	N
66183	Antisera, Fluorescent, Human Metapneumovirus	C	3	3	2	N	N
66184	Antisera, Fluorescent, Poliovirus 1-3	B	3	2	1	N	N
66185	Antisera, Fluorescent, Pseudomonas Aeruginosa	B	3	2	2	N	N
66186	Antisera, Fluorescent, Pseudomonas Pseudomallei	D	3	2	2	N	N
66187	Antisera, Fluorescent, Sporothrix Schenekii	B	3	2	1	N	N
66188	Antisera, Hai (Including Hai Control), Rubella	C	3	3	2	N	N
66189	Antisera, Hai, Adenovirus 1-33	B	3	2	1	N	N
66190	Antisera, Hai, Influenza Virus A, B, C	B	3	2	1	N	N
66191	Antisera, Hai, Parainfluenza Virus 1-4	B	3	2	1	N	N
66192	Antisera, Hai, Reovirus 1-3	B	3	2	1	N	N
66193	Antisera, If, Toxoplasma Gondii	C	2b	3	2	N	N
66194	Antisera, Immunoperoxidase, Chlamydia Spp.	C	2b	3	1	N	N
66195	Antisera, Latex Agglutination, Cryptococcus Neoformans	C	2b	3	2	N	N
66196	Antisera, Neutralization, Adenovirus 1-33	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66197	Antisera, Neutralization, All Types, Rhinovirus	B	3	2	1	N	N
66198	Antisera, Neutralization, Coxsackievirus A 1-24, B 1-6	B	2a	2	1	N	N
66199	Antisera, Neutralization, Echovirus 1-34	B	2a	2	1	N	N
66200	Antisera, Neutralization, Herpesvirus Hominis	C	2b	3	2	N	N
66201	Antisera, Neutralization, Influenza Virus A, B, C	B	2a	2	1	N	N
66202	Antisera, Neutralization, Parainfluenza Virus 1-4	B	2a	2	1	N	N
66203	Antisera, Neutralization, Poliovirus 1-3	B	2a	2	1	N	N
66204	Antisera, Neutralization, Rubella	C	2b	3	2	N	N
66205	Antisera, Neutralization, Reovirus 1-3	C	2b	3	1	N	N
66206	Antisera, Positive Control, Echinococcus Spp.	B	2a	2	1	N	N
66207	Antiserum, Bentonite Flocculation, Trichinella Spiralis	B	2a	2	1	N	N
66208	Antiserum, Blastomyces Dermatitidis, Other	B	2a	2	2	N	N
66209	Antiserum, Cf, Cytomegalovirus	C	2b	3	2	N	N
66210	Antiserum, Cf, Epstein-Barr Virus	C	2b	3	1	N	N
66211	Antiserum, Cf, Lymphocytic Choriomeningitis Virus	B	2a	2	1	N	N
66212	Antiserum, Cf, Mumps Virus	B	2a	2	1	N	N
66213	Antiserum, Cf, Psittacosis (Chlamydia Group)	C	2b	3	1	N	N
66214	Antiserum, Cf, Q Fever	B	2a	2	1	N	N
66215	Antiserum, Cf, Rubeola	B	2a	2	1	N	N
66216	Antiserum, Cf, Varicella-Zoster	B	2a	2	2	N	N
66217	Antiserum, Coagglutination (Direct) Neisseria Gonorrhoeae	C	2b	3	2	N	N
66218	Antiserum, Erysipelothrix Rhusiopathiae	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66219	Antiserum, Flavobacterium Meningosepticum, All Groups	B	2a	2	1	N	N
66220	Antiserum, Fluorescent (Direct Test), All Groups, N. Gonorrhoeae	C	2b	3	2	N	N
66221	Antiserum, Fluorescent, C. Diphtheriae	B	2a	2	1	N	N
66222	Antiserum, Fluorescent, Campylobacter Fetus	B	2a	2	1	N	N
66223	Antiserum, Fluorescent, Chlamydia Trachomatis	C	2b	3	1	N	N
66224	Antiserum, Fluorescent, Epstein-Barr Virus	C	2b	3	1	N	N
66225	Antiserum, Fluorescent, Erysipelothrix Rhusiopathiae	B	2a	2	1	N	N
66226	Antiserum, Fluorescent, Francisella Tularensis	B	2a	2	2	N	N
66227	Antiserum, Fluorescent, Mumps Virus	B	2a	2	1	N	N
66228	Antiserum, Fluorescent, Mycobacterium Tuberculosis	C	2b	3	1	N	N
66229	Antiserum, Fluorescent, Q Fever	B	2a	2	1	N	N
66230	Antiserum, Fluorescent, Rabies Virus	B	2a	2	2	N	N
66231	Antiserum, Fluorescent, Rubeola	B	2a	2	1	N	N
66232	Antiserum, Francisella Tularensis	B	2a	2	2	N	N
66233	Antiserum, Hai, Mumps Virus	B	2a	2	1	N	N
66234	Antiserum, Hai, Rubeola	B	2a	2	1	N	N
66235	Antiserum, Murine Typhus Fever	B	2a	2	1	N	N
66236	Antiserum, Neutralization, Mumps Virus	B	2a	2	1	N	N
66237	Antiserum, Neutralization, Respiratory Syncytial Virus	B	2a	2	1	N	N
66238	Antiserum, Neutralization, Rubeola	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66239	Antiserum, Positive And Negative Febrile Antigen Control Serum	B	2a	2	2	N	N
66240	Antiserum, Positive Control, Aspergillus Spp.	B	2a	2	1	N	N
66241	Antiserum, Positive Control, Blastomyces Dermatitidis	B	2a	2	2	N	N
66242	Antiserum, Positive Control, Coccidioides Immitis	B	2a	2	2	N	N
66243	Antiserum, Positive Control, Histoplasma Capsulatum	B	2a	2	2	N	N
66244	Antiserum, Pseudomonas Pseudomallei	B	2a	2	2	N	N
66245	Antiserum, Rickettsialpox	B	2a	2	1	N	N
66246	Antiserum, Rocky Mountain Spotted Fever	B	2a	2	1	N	N
66247	Antiserum, Typhus Fever	B	2a	2	1	N	N
66248	Antiserum, Vibrio Cholerae, All Varieties	B	2a	2	2	N	N
66249	Anti-Sm Antibody, Antigen And Control	B	2a	2	2	N	N
66250	Antismooth Muscle Antibody, Indirect Immunofluorescent, Antigen, Control	B	2a	2	2	N	N
66251	Anti-Ss-A 52 Autoantibodies	B	2a	2	2	N	N
66252	Anti-Streptokinase	B	2a	2	1	N	N
66253	Antistreptolysin - Titer/Streptolysin O Reagent	D	2a	2	1	N	N
66254	Assay, Direct, Nucleic Acid Amplification, Influenza Virus	D	2a	2	1	N	N
66255	Assay, Direct, Nucleic Acid Amplification, Parainfluenza Virus	D	2a	2	1	N	N
66256	Assay, Direct, Nucleic Acid Amplification, Q Fever	D	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66257	Assay, Direct, Nucleic Acid Amplification, Respiratory Syncytial Virus	D	2a	2	1	N	N
66258	Assay, Endotoxin Activity, Chemiluminescent	D	2a	2	2	N	N
66259	Assay, Enterovirus Nucleic Acid	D	2b	3	2	N	N
66260	Assay, Genotype, Hiv Drug Resistance, In Vitro	D	3	4	2	N	N
66261	Assay, Genotyping, Hepatitis C Virus	C	2b	3	U	N	N
66262	Assay, Nucleic Acid Amplification, Bacillus Anthracis	B	2a	2	2	N	N
66263	Assay, Nucleic Acid Amplification, Growth Identification, Mycobacterium Tuberculosis	C	2b	3	1	N	N
66264	Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus	D	3	4	3	N	N
66265	Assay, Enzyme Linked Immunosorbent, Parvovirus B19 Igg	B	2a	2	3	N	N
66266	Assay, Enzyme Linked Immunosorbent, Parvovirus B19 Igm	B	2a	2	3	N	N
66267	Assay, Hybridization And/Or Nucleic Acid Amplification For Detection Of Hepatitis C Rna, Hepatitis C Virus	D	3	4	3	N	N
66268	Autoantibodies, Acetylcholine Receptor, Acetylcholine Blocking And Non-Blocking	B	2a	2	2	N	N
66269	Autoantibodies, Anti-Ribonucleic Acid Polymerase (Rnap) Iii Antibody	B	2a	2	2	N	N
66270	Autoantibodies, Anti-Soluble Liver Antigen (Sla), Autoimmune Hepatitis	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66271	Autoantibodies, Endomysial(Tissue Transglutaminase)	B	2a	2	2	N	N
66272	Autoantibodies, Glutamic Acid Decarboxylase (Gad)	B	2a	2	2	N	N
66273	Autoantibodies, Nuclear Body Protein, Sp100	B	2a	2	2	N	N
66274	Autoantibodies, Nuclear Pore Glycoprotein Gp210	B	2a	2	2	N	N
66275	Autoantibodies, Skin (Bullous Pemphigoid 180 And Bullous Pemphigoid 230)	B	2a	2	2	N	N
66276	Autoantibodies,Lkm-1(Liver/Kidney Microsome,Type 1)	B	2a	2	2	N	N
66277	Autoantibodies,Skin(Desmoglein 1 And Desmoglein 3)	B	2a	2	2	N	N
66278	Auto-Antibodies; Phosphatidylserine, Prothrombin, Phosphatidylserine/Prothrombin Complex	B	2a	2	2	N	N
66279	Automated Colony Counter	B	2a	2	1	N	N
66280	Bacteriophage And Controls, B. Anthracis Lysis	C	2b	3	U	N	N
66281	Bath, Incubators/Water, All	A	1	1	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66282	Bcr/Abl1 Quantitative Monitoring Test	B	2a	2	U	N	N
66283	Bence-Jones Protein, Antigen, Antiserum, Control	B	2a	2	2	N	N
66284	Beta-2-Glycoprotein I, Antigen, Antiserum, Control	B	2a	2	1	N	N
66285	Beta-2-Glycoprotein Iii, Antigen, Antiserum, Control	B	2a	2	1	N	N
66286	Beta-Globulin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66287	Biosensor,Immunoassay,Myoglobin	C	2b	3	2	N	N
66288	Bordetella Pertussis Dna Assay System	B	2a	2	2	N	N
66289	Braf Mutation Kit	B	2a	2	U	N	N
66290	Breast Milk, Antigen, Antiserum, Control	B	2a	2	1	N	N
66291	Breast Milk, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N
66292	Breast Milk, Rhodamine, Antigen, Antiserum, Control	B	2a	2	1	N	N
66293	C. Difficile Nucleic Acid Amplification Test Assay	B	2a	2	1	N	N
66294	C. Trachomatis (Chlamydia Group)	C	2b	3	1	N	N
66295	C.Difficile Toxin Gene Amplification Assay	C	2b	3	2	N	N
66296	C3-Indirect Immunofluorescent Solid Phase	B	2a	2	2	N	N
66297	Calibrator For Alpha-Fetoprotein In Mid-Pregnancy Maternal Serum	C	2b	3	3	N	N
66298	Calprotectin, Fecal	B	2a	2	2	N	N
66299	Campylobacter Spp.	B	2a	2	1	N	N
66300	Cancer Monitoring Test System, Soluble Mesothelin-Related Peptides, Epithelioid/Biphasic Mesothelioma	C	2b	3	f	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66301	Cancer Monitoring Test System, Soluble Mesothelin-Related Peptides, Mesothelioma	C	2b	3	2	N	N
66302	Candida Species, Antibody Detection	B	2a	2	2	N	N
66303	Candida Spp., Direct Antigen, Id	B	2a	2	2	N	N
66304	Carbonic Anhydrase B, Antigen, Antiserum, Control	B	2a	2	1	N	N
66305	Carbonic Anhydrase C, Antigen, Antiserum, Control	B	2a	2	1	N	N
66306	Cardiac C-Reactive Protein, Antigen, Antiserum, And Control	B	2a	2	2	N	N
66307	Ceruloplasmin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66308	Ceruloplasmin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66309	Ceruloplasmin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66310	Chlamydomyxa Pneumoniae Dna Assay System	B	2a	2	2	N	N
66311	Chromogenic In Situ Hybridisation, Nucleic Acid Amplification, Her2/Neu Gene, Breast Cancer	C	2b	3	3	N	N
66312	Chronic Lymphocytic Leukemia Fish Probe Kit	B	2a	2	2	N	N
66313	Classifier, Prognostic, Recurrence Risk Assessment, Rna Gene Expression, Breast Cancer	B	2a	2	2	N	N
66314	Cohn Fraction Ii, Antigen, Antiserum, Control	B	2a	2	1	N	N
66315	Colostrum, Antigen, Antiserum, Control	B	2a	2	1	N	N
66316	Complement 4d (C4d) And Complement Receptor 1 (Cr1)	B	2a	2	2	N	N
66317	Complement C1 Inhibitor (Inactivator), Antigen, Antiserum, Control	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66318	Complement C1q, Antigen, Antiserum, Control	B	2a	2	2	N	N
66319	Complement C1r, Antigen, Antiserum, Control	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66320	Complement C1s, Antigen, Antiserum, Control	B	2a	2	2	N	N
66321	Complement C3, Antigen, Antiserum, Control	B	2a	2	2	N	N
66322	Complement C3b Activator Immunoassay Reagents	B	2a	2	2	N	N
66323	Complement C3b Activator, Antigen, Antiserum, Control	B	2a	2	2	N	N
66324	Complement C4, Antigen, Antiserum, Control	B	2a	2	2	N	N
66325	Complement C5, Antigen, Antiserum, Control	B	2a	2	2	N	N
66326	Complement C8, Antigen, Antiserum, Control	B	2a	2	2	N	N
66327	Complement C9, Antigen, Antiserum, Control	B	2a	2	2	N	N
66328	C-Reactive Protein, Antigen, Antiserum, And Control	B	2a	2	2	N	N
66329	Cryptosporidium Spp.	B	2a	2	2	N	N
66330	Culture Media, Anaerobic Transport	A	1	1	1	N	N
66331	Culture Media, Antibiotic Assay	A	1	1	1	N	N
66332	Culture Media, Antifungal, Susceptibility Test	B	2a	2	2	N	N
66333	Culture Media, Antimicrobial Susceptibility Test	B	2a	2	2	N	N
66334	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar	B	2a	2	2	N	N
66335	Culture Media, Antimicrobial Susceptibility Test, Mueller Hinton Agar/Broth	A	1	1	2	N	N
66336	Culture Media, Antimycobacteria, Susceptibility Test	B	2a	2	2	N	N
66337	Culture Media, Enriched	A	1	1	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66338	Culture Media, For Isolation Of Pathogenic Neisseria	A	1	1	2	N	N
66339	Culture Media, General Nutrient Broth	A	1	1	1	N	N
66340	Culture Media, Multiple Biochemical Test	A	1	1	1	N	N
66341	Culture Media, Non-Propagating Transport	A	1	1	1	N	N
66342	Culture Media, Non-Selective And Differential	A	1	1	1	N	N
66343	Culture Media, Non-Selective And Non-Differential	A	1	1	1	N	N
66344	Culture Media, Propagating Transport	A	1	1	1	N	N
66345	Culture Media, Selective And Differential	A	1	1	1	N	N
66346	Culture Media, Selective And Non-Differential	A	1	1	1	N	N
66347	Culture Media, Selective Broth	A	1	1	1	N	N
66348	Culture Media, Single Biochemical Test	A	1	1	1	N	N
66349	Culture Media, Vitamin Assay	A	1	1	1	N	N
66350	Cytokeratin Fragments 21-1 Eia Kit	B	2a	2	2	N	N
66351	Cytokeratins	B	2a	2	2	N	N
66352	D/Km-1, Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66353	Dengue Nucleic Acid Amplification Assay (Naat)	C	2b	3	2	N	N
66354	Dengue Serological Reagents	C	2b	3	2	N	N
66355	Des-Gamma-Carboxy-Prothrombin (Dcp), Risk Assessment, Hepatocellular Carcinoma	B	2a	2	2	N	N
66356	Device, Antimicrobial Drug Removal	A	1	1	1	N	N
66357	Device, Gas Generating	B	2a	2	1	N	N
66358	Device, General Purpose, Hematology	B	2a	2	2	N	N
66359	Device, General Purpose, Microbiology, Diagnostic	B	2a	2	1	N	N
66360	Device, Media Dispensing/Stacking	A	1	1	1	N	N
66361	Device, Microtiter Diluting/Dispensing	A	1	1	1	N	N
66362	Device, Oxidase Test For Gonorrhea	C	2b	3	3	N	N
66363	Device, Parasite Concentration	B	2a	2	1	N	N
66364	Device, Specimen Collection	A	1	1	1	N	N
66365	Devices, Measure, Antibodies To Glomerular Basement Membrane (Gbm)	B	2a	2	2	N	N
66366	Direct Agglutination Test, Toxoplasma Gondii	C	2b	3	2	N	N
66367	Discs, Elution	B	2a	2	2	N	N
66368	Discs, Strips And Reagents, Microorganism Differentiation	B	2a	2	1	N	N
66369	Dna Probe, Gardnerella Vaginalis	B	2a	2	1	N	N
66370	Dna Probe, Nucleic Acid Amplification, Chlamydia	C	2b	3	1	N	N
66371	Dna Probe, Trichomonas Vaginalis	B	2a	2	1	N	N
66372	Dna Probe, Yeast	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66373	Dna-Probe - Blastomyces Dermatitis	B	2a	2	2	N	N
66374	Dna-Probe Kit, Human Chromosome	B	2a	2	2	N	N
66375	Dna-Probe Kit, Human Chromosome X And Y, Bmt Engraftment	B	2a	2	2	N	N
66376	Dna-Probe, Agent, Listeria	C	2b	3	1	N	N
66377	Dna-Probe, Haemophilus Spp.	B	2a	2	2	N	N
66378	Dna-Probe, Reagent, Histoplasma Capsulatum	B	2a	2	2	N	N
66379	Dna-Probe, Reagents, Coccidioides Immitis	B	2a	2	2	N	N
66380	Dna-Probe, Reagents, Cryptococcal	C	2b	3	2	N	N
66381	Dna-Probe, Reagents, Streptococcal	C	2b	3	1	N	N
66382	Dna-Probe, Staphylococcus Aureus	C	2b	3	1	N	N
66383	Dna-Probe, Strep Pneumoniae	C	2b	3	1	N	N
66384	Dna-Reagents, Campylobacter Spp.	B	2a	2	1	N	N
66385	Dna-Reagents, Chlamydia	C	2b	3	1	N	N
66386	Dna-Reagents, Cytomegalovirus	B	2a	2	2	N	N
66387	Dna-Reagents, Epstein-Barr Virus	C	2b	3	1	N	N
66388	Dna-Reagents, Legionella	C	2b	3	2	N	N
66389	Dna-Reagents, Mycobacterium Spp.	C	2b	3	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66390	Dna-Reagents, Mycoplasma Spp.	B	2a	2	1	N	N
66391	Dna-Reagents, Neisseria	C	2b	3	2	N	N
66392	Dna-Reagents, Salmonella Spp.	B	2a	2	2	N	N
66393	Dna-Reagents, Shigella Spp.	B	2a	2	2	N	N
66394	Early Growth Response 1 (Egr) Fish Probe Kit	B	2a	2	2	N	N
66395	Eia, Blastomyces Dermatitidis	B	2a	2	2	N	N
66396	Electrophoresis Instrumentation	B	2a	2	1	N	N
66397	Elisa, Antibody, West Nile Virus	C	2b	3	2	N	N
66398	Elisa, Trichinella Spiralis	B	2a	2	1	N	N
66399	Enzyme Immunoassay, Antiparietal Cell Antibody, Antigen, Control	B	2a	2	2	N	N
66400	Enzyme Immunoassay, Methotrexate	B	2a	2	U	N	N
66401	Enzyme Linked Immunoabsorbent Assay, (Chlamydiae Group)	C	2b	3	1	N	N
66402	Enzyme Linked Immunoabsorbent Assay, Antibody, B. Anthracis	C	2b	3	U	N	N
66403	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus	C	2b	3	2	N	N
66404	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-Specific	C	2b	3	2	N	N
66405	Enzyme Linked Immunoabsorbent Assay, Histoplasma Capsulatum	B	2a	2	2	N	N
66406	Enzyme Linked Immunoabsorbent Assay, Mumps Virus	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66407	Enzyme Linked Immunoabsorbent Assay, Mycoplasma Spp.	B	2a	2	1	N	N
66408	Enzyme Linked Immunoabsorbent Assay, Rotavirus	B	2a	2	1	N	N
66409	Enzyme Linked Immunoabsorbent Assay, Rubella	C	2b	3	2	N	N
66410	Enzyme Linked Immunoabsorbent Assay, Rubeola Igg	B	2a	2	1	N	N
66411	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii	C	2b	3	2	N	N
66412	Enzyme Linked Immunoabsorbent Assay, Varicella-Zoster	B	2a	2	2	N	N
66413	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum	C	2b	3	2	N	N
66414	Enzyme Linked Immunosorbent Assay For The Detection Of Lipoarabinomannan Antigen Of Mycobacteria	C	2b	3	3	N	N
66415	Enzyme Linked Immunosorbent Assay, Coccidioides Immitis	B	2a	2	2	N	N
66416	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1	B	2a	2	2	N	N
66417	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2	C	2b	3	2	N	N
66418	Enzyme Linked Immunosorbent Assay, T. Cruzi	D	3	4	1	N	N
66419	Epstein-Barr Virus, Other	C	2b	3	1	N	N
66420	Equipment, Rocket Immunoelectrophoresis	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66421	Erythrocyte Suspension, Multi Species, Serological Reagent And Equipment	B	2a	2	1	N	N
66422	Exoenzymes, Multiple, Streptococcal	B	2a	2	1	N	N
66423	Extractable Antinuclear Antibody, Antigen And Control	B	2a	2	2	N	N
66424	Fab, Antigen, Antiserum, Control	B	2a	2	1	N	N
66425	Fab, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N
66426	Fab, Rhodamine, Antigen, Antiserum, Control	B	2a	2	1	N	N
66427	Factor B, Antigen, Antiserum, Control	B	2a	2	2	N	N
66428	Factor Xiii A, S, Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66429	Fc, Antigen, Antiserum, Control	B	2a	2	1	N	N
66430	Fc, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N
66431	Fc, Rhodamine, Antigen, Antiserum, Control	B	2a	2	1	N	N
66432	Ferritin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66433	Fibrinopeptide A, Antigen, Antiserum, Control	B	2a	2	2	N	N
66434	Fish (Fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Enterococcus Faecalis	B	2a	2	1	N	N
66435	Fish (Fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Rna, Staphylococcus Aureus	C	2b	3	1	N	N
66436	Fish (Fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Rna, Yeast	B	2a	2	1	N	N
66437	Fluorescence In Situ Hybridization, Anaplastic Lymphoma Kinase, Gene Rearrangement	C	2b	3	3	N	N
66438	Fluorescence In Situ Hybridization, Topoisomerase Ii Alpha, Gene Amplification And Deletion	C	2b	3	3	N	N
66439	Fluorometer	A	1	1	1	N	N
66440	For Export Only - Antigen, Anti-Cardiac, Indirect Fluorescent Antibody Test System	B	2a	2	U	N	N
66441	For Export Only - Antigen, Anti-Skeletal, Indirect Fluorescent Antibody Test System	B	2a	2	U	N	N
66442	Fraction Iv-5, Antigen, Antiserum, Control	B	2a	2	1	N	N
66443	Fraction V, Antigen, Antiserum, Control	B	2a	2	1	N	N
66444	Free Secretory Component, Antigen, Antiserum, Control	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66445	Gamma Globulin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66446	Gamma Globulin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66447	Gas Chromatography, Bacillus Anthracis Membrane Fatty Acids	C	2b	3	U	N	N
66448	Giardia Spp.	B	2a	2	2	N	N
66449	Gonococcal Antibody Tests	C	2b	3	3	N	N
66450	Gram Negative Identification Panel	B	2a	2	1	N	N
66451	Gram Positive Identification Panel	B	2a	2	1	N	N
66452	Gram-Positive Bacteria And Their Resistance Markers	B	2a	2	2	N	N
66453	Group A Streptococcus Nucleic Acid Amplification Assay System	C	2b	3	1	N	N
66454	Haptoglobin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66455	Haptoglobin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66456	Haptoglobin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66457	Helicobacter Pylori	B	2a	2	1	N	N
66458	Hemoglobin, Chain Specific, Antigen, Antiserum, Control	B	2a	2	2	N	N
66459	Hemopexin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66460	Hemopexin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66461	Hemopexin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66462	Hepatitis A Test (Antibody And Igm Antibody)	B	2a	2	2	N	N
66463	Hepatitis Delta Serological Reagents	C	2b	3	3	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66464	Hepatitis Viral B Dna Detection	D	3	4	3	N	N
66465	Herpes Simplex Virus Nucleic Acid Amplification Assay	C	2b	3	2	N	N
66466	Human Metapneumovirus (Hmpv) Rna Assay System	C	2b	3	2	N	N
66467	Iga, Antigen, Antiserum, Control	B	2a	2	2	N	N
66468	Iga, Ferritin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66469	Iga, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66470	Iga, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66471	Iga, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66472	Igal Heavy & Light Chain Combined	B	2a	2	2	N	N
66473	Igd, Antigen, Antiserum, Control	B	2a	2	2	N	N
66474	Igd, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66475	Igd, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66476	Igd, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66477	Ige, Antigen, Antiserum, Control	B	2a	2	2	N	N
66478	Ige, Ferritin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66479	Ige, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66480	Ige, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66481	Ige, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66482	Igg (Fab Fragment Specific), Antigen, Antiserum, Control	B	2a	2	1	N	N
66483	Igg (Fc Fragment Specific), Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66484	Igg (Fd Fragment Specific), Antigen, Antiserum, Control	B	2a	2	1	N	N
66485	Igg (Gamma Chain Specific), Antigen, Antiserum, Control	B	2a	2	2	N	N
66486	Igg, Antigen, Antiserum, Control	B	2a	2	2	N	N
66487	Igg, Ferritin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66488	Igg, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66489	Igg, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66490	Igg, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66491	Igm (Mu Chain Specific), Antigen, Antiserum, Control	B	2a	2	2	N	N
66492	Igm, Antigen, Antiserum, Control	B	2a	2	2	N	N
66493	Igm, Ferritin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66494	Igm, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66495	Igm, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66496	Igm, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66497	Immunoassay For Blood Tacrolimus	C	2b	3	N	N	Y
66498	Immunochemical, Bence-Jones Protein	B	2a	2	2	N	N
66499	Immunochemical, Ceruloplasmin	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66500	Immunochemical, Thyroglobulin Autoantibody	B	2a	2	2	N	N
66501	Immunochemical, Transferrin	B	2a	2	2	N	N
66502	Immunochemical, Transferrin	B	2a	2	2	N	N
66503	Immunofluorescent Assay, T. Cruzi	C	2b	3	1	N	N
66504	Immunoglobulin A Kappa Heavy & Light Chain Combined	B	2a	2	2	N	N
66505	Immunohistochemical Assay, Helicobacter Pylori	B	2a	2	1	N	N
66506	Indirect Copper Assay, Ceruloplasmin	B	2a	2	2	N	N
66507	Indirect Fluorescent Antibody Test, Entamoeba Histolytica & Rel Sp	B	2a	2	2	N	N
66508	Influenza A And Influenza B Multiplex Nucleic Acid Assay	B	2a	2	2	N	N
66509	Influenza A Virus Subtype Differentiation Nucleic Acid Assay	B	2a	2	2	N	N
66510	Instrument For Auto Reader & Interpretation Of Overnight Suscept. Systems	B	2a	2	2	N	N
66511	Instrument For Auto Reader Of Overnight Microorganism Identification System	B	2a	2	1	N	N
66512	Insulin Autoantibody Kit	B	2a	2	2	N	N
66513	Inter-Alpha Trypsin Inhibitor, Antigen, Antiserum, Control	B	2a	2	1	N	N
66514	Inter-Alpha Trypsin Inhibitor, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66515	Joint Biological Agent Identification And Diagnostic System (Jbaid) Tularemia Detection Kit	C	2b	3	2	N	N
66516	Kappa, Antigen, Antiserum, Control	B	2a	2	2	N	N
66517	Kappa, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66518	Kappa, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66519	Kappa, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66520	Kit, Anaerobic Identification	B	2a	2	1	N	N
66521	Kit, Dna Detection, Human Papillomavirus	C	2b	3	3	N	N
66522	Kit, Fastidious Organisms	B	2a	2	1	N	N
66523	Kit, Identification, Dermatophyte	B	2a	2	1	N	N
66524	Kit, Identification, Enterobacteriaceae	B	2a	2	1	N	N
66525	Kit, Identification, Glucose Nonfermenter	B	2a	2	1	N	N
66526	Kit, Identification, Mycobacteria	C	2b	3	1	N	N
66527	Kit, Identification, Neisseria Gonorrhoeae	C	2b	3	1	N	N
66528	Kit, Identification, Pseudomonas	C	2b	3	1	N	N
66529	Kit, Identification, Yeast	B	2a	2	1	N	N
66530	Kit, Immunochromatographic, Bacillus Anthracis Differential Antibody	C	2b	3	U	N	N
66531	Kit, Quality Control For Culture Media	B	2a	2	1	N	N
66532	Kit, Rna Detection, Human Papillomavirus	C	2b	3	3	N	N
66533	Kit, Sample Collection, Hiv	C	2b	3	3	N	N
66534	Kit, Screening, Staphylococcus Aureus	B	2a	2	1	N	N
66535	Kit, Screening, Trichomonas	B	2a	2	1	N	N
66536	Kit, Screening, Urine	B	2a	2	1	N	N
66537	Kit, Screening, Yeast	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66538	Kit, Test, Alpha-Fetoprotein For Neural Tube Defects	C	2b	3	3	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66539	Kit, Test,Alpha-Fetoprotein For Testicular Cancer	C	2b	3	2	N	N
66540	Kit,Antibody,Elution	B	2a	2	U	N	N
66541	Kit,Test For Nuclear Matrix(Numa)Protein(For Monitoring And Management Of Colorectal Cancer	B	2a	2	2	N	N
66542	Kit,Test(Donors),For Bloodborne Pathogen	D	3	4	2	N	N
66543	Kit,Test,Quality Control For Endotoxin	C	2b	3	U	N	N
66544	Kit,Test,Saliva,Hiv-1&2	D	3	4	U	N	N
66545	Kit,Typing,Hla-Dqb	C	2b	3	2	N	N
66546	Kit,Western Blot,Hiv-1	D	3	4	U	N	N
66547	Lactic Dehydrogenase, Antigen, Antiserum, Control	B	2a	2	1	N	N
66548	Lactoferrin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66549	Lambda, Antigen, Antiserum, Control	B	2a	2	2	N	N
66550	Lambda, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66551	Lambda, Peroxidase, Antigen, Antiserum, Control	B	2a	2	2	N	N
66552	Lambda, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66553	Latex Agglutination Assay, Rubella	C	2b	3	2	N	N
66554	Legionella, Spp., Elisa	C	2b	3	2	N	N
66555	Leukemia Translocation Panel Multiplex Test	B	2a	2	U	N	N
66556	Light, Wood'S, Fluorescence	A	1	1	1	N	N
66557	Lipoprotein X, Antigen, Antiserum, Control	B	2a	2	1	N	N
66558	Lipoprotein, Low-Density, Antigen, Antiserum, Control	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66559	Manual Antimicrobial Susceptibility Test Systems	B	2a	2	2	N	N
66560	Manual Colony Counter	B	2a	2	1	N	N
66561	Media, Culture, Amino Acid Assay	A	1	1	1	N	N
66562	Methicillin Resistant Staphylococcus Aureus/Methicillin Susceptible Staphylococcus Aureus Blood Culture Test Bt	C	2b	3	1	N	N
66563	Method, Immunodiffusion, Immunoglobulins (G, A, M)	B	2a	2	2	N	N
66564	Method, Nephelometric, Immunoglobulins (G, A, M)	B	2a	2	2	N	N
66565	Monitor, Microbial Growth	A	1	1	1	N	N
66566	Monitor, Test, Hiv-1	C	2b	3	3	N	N
66567	Monoclonal, Hiv-1	D	3	4	N	N	N
66568	Multiple Autoantibodies, Indirect Immunofluorescent, Antigen, Control	B	2a	2	2	N	N
66569	Multiplex Flow Immunoassay, T.Gondii, Rubella And Cmv.	C	2b	3	2	N	N
66570	Multiplex Immunoassay For Measles Virus, Mumps Virus, Rubella And Varicella Zoster Virus	C	2b	3	2	N	N
66571	Multiplex Immunoassay For T. Gondii, Rubella, Cytomegalovirus And Herpes Simplex Virus 1 And 2	C	2b	3	2	N	N
66572	Mycobacterium Tuberculosis, Cell Mediated Immune Response, Enzyme-Linked Immunospot Test	C	2b	3	3	N	N
66573	Mycoplasma Pneumoniae Dna Assay System	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66574	Myeloperoxidase, Immunoassay, System, Test	B	2a	2	2	N	N
66575	Myoglobin, Antigen, Antiserum, Control	C	2b	3	2	N	N
66576	Myoglobin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66577	Myoglobin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66578	Neisseria Controls	C	2b	3	1	N	N
66579	Nephelometer	A	1	1	1	N	N
66580	Ng1m(A), Antigen, Antiserum, Control	B	2a	2	1	N	N
66581	Ng3m(Bo), Antigen, Antiserum, Control	B	2a	2	1	N	N
66582	Ng3m(G), Antigen, Antiserum, Control	B	2a	2	1	N	N
66583	Ng4m(A), Antigen, Antiserum, Control	B	2a	2	1	N	N
66584	Non-Sars Coronavirus Multiplex Nucleic Acid Assay	C	2b	3	2	N	N
66585	Norovirus Serological Reagent	B	2a	2	2	N	N
66586	Novel Influenza A Virus, A/H5 Ns1 Protein	B	2a	2	2	N	N
66587	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test	C	2b	3	1	N	N
66588	Nucleic Acid Amplification, Novel Influenza A Virus, A/H5 (Asian Lineage) Rna	B	2a	2	2	N	N
66589	Nucleic Amplification Assays For The Detection Of Leishmania Nucleic Acids	B	2a	2	1	N	N
66590	Ovarian Adnexal Mass Assessment Score Test System	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66591	P2psa	C	2b	2	3	N	N
66592	Panels, Test, Susceptibility, Antimicrobial	B	2a	2	2	N	N
66593	Parainfluenza Multiplex Nucleic Acid Assay	B	2a	2	2	N	N
66594	Phages, Staphylococcal Typing, All Types	B	2a	2	1	N	N
66595	Plasma, Coagulase, Human, Horse And Rabbit	B	2a	2	1	N	N
66596	Plasminogen, Antigen, Antiserum, Control	B	2a	2	1	N	N
66597	Plasmodium Spp. Detection Reagents	B	2a	2	2	N	N
66598	Plates And Equipment, Radial Immunodiffusion	B	2a	2	1	N	N
66599	Plates, Ouchterlony Agar	B	2a	2	1	N	N
66600	Pneumocystis Carinii	B	2a	2	2	N	N
66601	P-Phenyl-Enediamine/Edta (Spectrophotometric), Ceruloplasmin	B	2a	2	2	N	N
66602	Prealbumin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66603	Prealbumin, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N
66604	Prostate-Specific Antigen (Psa) For Management Of Prostate Cancers	C	2b	3	2	N	N
66605	Prostate-Specific Antigen (Psa) For Prognostic, Recurrence Risk Assessment Of Prostate Cancers	C	2b	3	2	N	N
66606	Protein, Complement, Antigen, Antiserum, Control	B	2a	2	1	N	N
66607	Prothrombin, Antigen, Antiserum, Control	B	2a	2	1	N	N
66608	Quality Control Material, Genetics, Dna	B	2a	2	2	N	N
66609	Quality Control Slides	A	1	1	1	N	N
66610	Radioassay, Methotrexate, Enzyme	B	2a	2	U	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66611	Radioimmunoassay (Two-Site Solid Phase), Ferritin	B	2a	2	2	N	N
66612	Radioimmunoassay, Immunoglobulins (D, E)	B	2a	2	2	N	N
66613	Radioimmunoassay, Immunoglobulins (G, A, M)	B	2a	2	2	N	N
66614	Radioimmunoassay, Netilmicin (I-125)	B	2a	2	U	N	N
66615	Radioimmunoassay, Sisomicin	B	2a	2	U	N	N
66616	Reader, Zone, Automated	A	1	1	1	N	N
66617	Reagent, Borrelia Serological Reagent	B	2a	2	2	N	N
66618	Reagent, Complement	B	2a	2	1	N	N
66619	Reagent, Immunoassay, Carbonic Anhydrase B And C	B	2a	2	1	N	N
66620	Reagent, Immunoassay, Igg	B	2a	2	1	N	N
66621	Reagent, Leishmanii Serological	B	2a	2	1	N	N
66622	Reagent, Rickettsia Serological	B	2a	2	1	N	N
66623	Reagent, Blood Bank, Quality Control	C	2b	3	U	N	N
66624	Reagent/Device, Inoculum Calibration	A	1	1	2	N	N
66625	Reagents, 2009 H1n1 Influenza Virus (Swine Origin), Nucleic Acid Or Antigen, Detection And Identification	C	2b	3	U	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66626	Reagents, Antibody, Legionella, Direct & Indirect Fluorescent	C	2b	3	2	N	N
66627	Reagents, Clostridium Difficile Toxin	C	2b	3	1	N	N
66628	Reagents, Cysticercosis	B	2a	2	1	N	N
66629	Research Use Only/Immunology Devices	B	2a	2	U	N	N
66630	Research Use Only/Microbiology	U	U	U	U	N	N
66631	Respiratory Syncytial Virus - Elisa	B	2a	2	1	N	N
66632	Respiratory Syncytial Virus, Antigen, Antibody, IFA	B	2a	2	1	N	N
66633	Respiratory Virus Panel Nucleic Acid Assay System	B	2a	2	2	N	N
66634	Retinol-Binding Protein, Antigen, Antiserum, Control	B	2a	2	1	N	N
66635	Rt-Pcr Multigene Expression Test, Sentinel Lymph Node, Cancer Metastasis Detection	C	2b	3	3	N	Y
66636	Rubella, Other Assays	C	2b	3	2	N	N
66637	Second Antibody (Species Specific Anti-Animal Gamma Globulin)	B	2a	2	2	N	N
66638	Seminal Fluid, Antigen, Antiserum, Control	B	2a	2	1	N	N
66639	Sera, Reactive And Non-Specific Control, Fta-Abs Test	C	2b	3	2	N	N
66640	Sex Crimes/Sexual Assault/Suspect Evidence Collection Kit (Excludes Hive Testing)	B	2a	2	1	N	N
66641	Solution, Antimicrobial	B	2a	2	2	N	N
66642	Sperm, Antigen, Antiserum, Control	B	2a	2	1	N	N
66643	Sperm, Fitc, Antigen, Antiserum, Control	B	2a	2	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66644	Staphylococcus Aureus Protein A Insoluble	C	2b	3	1	N	N
66645	Staphylococcus Aureus Somatic Antigens	B	2a	2	1	N	N
66646	Strip, Hama Igg, Elisa, In Vitro Test System	B	2a	2	2	N	N
66647	Strip, Virulence, Corynebacterium Diphtheriae	B	2a	2	1	N	N
66648	Supplement, Culture Media	A	1	1	1	N	N
66649	Support Gels	A	1	1	1	N	N
66650	Susceptibility Test Cards, Antimicrobial	B	2a	2	2	N	N
66651	Susceptibility Test Discs, Antimicrobial	B	2a	2	2	N	N
66652	Susceptibility Test Plate, Antifungal	B	2a	2	2	N	N
66653	Susceptibility Test Powders, Antimicrobial	A	1	1	2	N	N
66654	Susceptibility Test Powders, Antimycobacterial	B	2a	2	2	N	N
66655	System, Automated Scanning Microscope And Image Analysis For Fluorescence In Situ Hybridization (Fish) Assays	C	2b	3	2	N	N
66656	System, Blood Collection, Rna Stabilization, Rna Purification, Rt-Pcr Molecular Diagnostic Test	B	2a	2	2	N	N
66657	System, Blood Culturing	B	2a	2	1	N	N
66658	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection	B	2a	2	2	N	N
66659	System, Immunomagnetic, Circulating Cancer Cell, Enumeration	B	2a	2	2	N	N
66660	System, Mycolic Acid Analysis, Mycobacterium Tuberculosis	C	2b	3	1	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66661	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen	C	2b	3	2	N	N
66662	System, Nucleic Acid Amplification, Mycobacterium Tuberculosis Complex	C	2b	3	3	N	N
66663	System, Test, Alpha-Fetoprotein, Ria	C	2b	3	3	N	N
66664	System, Test, Anticardiolipin Immunological	B	2a	2	2	N	N
66665	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation	B	2a	2	2	N	N
66666	System, Test, Beta-2-Microglobulin Immunological	B	2a	2	2	N	N
66667	System, Test, Carbohydrate Antigen (Ca19-9), For Monitoring And Management Of Pancreatic Cancer	B	2a	2	2	N	N
66668	System, Test, Carcinoembryonic Antigen	C	2b	3	2	N	N
66669	System, Test, C-Reactive Protein	B	2a	2	2	N	N
66670	System, Test, C-Reactive Protein, Rhodamine	B	2a	2	2	N	N
66671	System, Test, Fibrin/Fibrinogen Degradation Products For Monitoring Of Colorectal Cancer	C	2b	3	2	N	N
66672	System, Test, Genotypic Detection, Resistant Markers, Enterococcus Species	B	2a	2	2	N	N
66673	System, Test, Her-2/Neu, Ihc	C	2b	3	3	N	N
66674	System, Test, Her-2/Neu, Monitoring	C	2b	3	2	N	N
66675	System, Test, Her-2/Neu, Nucleic Acid Or Serum	C	2b	3	3	N	N
66676	System, Test, Hypersensitivity Pneumonitis	B	2a	2	2	N	N
66677	System, Test, Immunological, Antigen, Tumor	B	2a	2	2	N	N
66678	System, Test, Infectious Mononucleosis	B	2a	2	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66679	System, Test, Radioallergosorbent (Rast) Immunological	B	2a	2	2	N	N
66680	System, Test, Rheumatoid Factor	B	2a	2	2	N	N
66681	System, Test, Systemic Lupus Erythematosus	B	2a	2	2	N	N
66682	System, Test, Thyroid Autoantibody	B	2a	2	2	N	N
66683	System, Test, Tumor Marker, Monitoring, Bladder	C	2b	3	2	N	N
66684	System, Transport, Aerobic	A	1	1	1	N	N
66685	System, Identification, Hepatitis B Antigen	D	3	4	3	N	N
66686	System, Test, Antibodies, B2 - Glycoprotein I (B2 - Gpi)	B	2a	2	2	N	N
66687	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies	B	2a	2	2	N	N
66688	System, Test, Home, Hiv-1	D	3	4	3	N	N
66689	System, Test, Thyroglobulin	B	2a	2	2	N	N
66690	System, Test, Tumor Marker, For Detection Of Bladder Cancer	C	2b	3	3	N	N
66691	T-Cell Xtend Reagent	C	2b	3	3	N	N
66692	Test Reagents, Neisseria Gonorrhoeae Biochemical	C	2b	3	1	N	N
66693	Test System, Antineutrophil Cytoplasmic Antibodies (Anca)	B	2a	2	2	N	N
66694	Test, Alpha Fetoprotein L3 Subfraction (Afp-L3%), For Hepatocellular Carcinoma Risk Assessment	C	2b	3	2	N	N
66695	Test, Antigen, Nuclear, Epstein-Barr Virus	C	2b	3	1	N	N
66696	Test, Anti-Tumor Cell Susceptibility	B	2a	2	3	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66697	Test, Epithelial Ovarian Tumor Associated Antigen (He4)	B	2a	2	2	N	N
66698	Test, Epithelial Ovarian Tumor-Associated Antigen (Ca125)	C	2b	3	2	N	N

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866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66699	Test, Hepatitis B (B Core, Be Antigen, Be Antibody, B Core Igm)	D	3	4	3	N	N
66700	Test, Hiv Detection	D	3	4	3	N	N
66701	Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis	C	2b	3	3	N	N
66702	Test, Malaria	B	2a	2	U		N
66703	Test, Nr2 Antibody	B	2a	2	U	N	N
66704	Test, Qualitative, Detection Of Dengue Igm And Igg Antibodies	C	2b	3	3	N	N
66705	Test, Sorbent, Fta-Abs	C	2b	3	2	N	N
66706	Test, Syphilis, Treponemal	C	2b	3	U	N	N
66707	Test, System, Immunoassay, Lipoprotein-Associated Phospholipase A2	B	2a	2	2	N	N
66708	Test, Urea (Breath Or Blood)	B	2a	2	1	N	N
66709	Test, Urea Adult And Pediatric (Breath),	B	2a	2	3	N	N
66710	Test, Donor, Cmv	D	3	4	2	N	N
66711	Test, Donor, Syphilis, Antigens, Treponemal	D	3	4	2	N	N
66712	Test, Equipment, Automated Bloodborne Pathogen	D	3	4	U	N	N
66713	Test, Platelet Antibody	B	2a	2	2	N	N
66714	Test, Prostate Specific Antigen, Free, (Noncomplexed) To Distinguish Prostate Cancer From Benign Conditions	C	2b	3	3	N	N
66715	Test, Vaginal, Bacterial Sialidase	B	2a	2	1	N	N
66716	Thyroglobulin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66717	Thyroglobulin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
866 IMMUNOLOGY AND MICROBIOLOGY DEVICES							
66718	Thyroglobulin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66719	Tissue Rna Preservative For Collection, Storage, And Transportation	B	2a	2	2	N	N
66720	Total Spinal-Fluid, Antigen, Antiserum, Control	B	2a	2	1	N	N
66721	Total,Prostate Specific Antigen(Noncomplexed&Complexed) For Detection Of Prostate Cancer	C	2b	3	3	N	N
66722	Transferrin, Antigen, Antiserum, Control	B	2a	2	2	N	N
66723	Transferrin, Fitc, Antigen, Antiserum, Control	B	2a	2	2	N	N
66724	Transferrin, Rhodamine, Antigen, Antiserum, Control	B	2a	2	2	N	N
66725	Transport Systems, Anaerobic	A	1	1	1	N	N
66726	Trichomonas Vaginalis Nucleic Acid Amplification Test System	B	2a	2	2	N	N
66727	Tryptase Assay System	B	2a	2	2	N	N
66728	Tyrosine Phosphatase (Ia-2) Autoantibody Assay	B	2a	2	2	N	N
66729	Voltage Gated Calcium Channel (Vgcc) Antibody Assay	B	2a	2	2	N	N
66730	Whole Blood Plasma, Antigen, Antiserum, Control	B	2a	2	1	N	N
66731	Whole Human Serum, Antigen, Antiserum, Control	B	2a	2	1	N	N
66732	Yersinia Spp. Reagents	B	2a	2	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68001	Absorbent, Carbon-Dioxide	B	2a	2	1	N	N
68018	Absorber, Carbon-Dioxide	C	2b	3	2	N	N
68003	Accessory To Continuous Ventilator (Respirator)	B	2a	2	2	N	N
68004	Airway Monitoring System	B	2a	2	2	N	N
68005	Airway Suction Kit	B	2a	2	1	N	N
68006	Airway, Esophageal (Obturator)	B	2a	2	2	N	Y
68007	Airway, Nasopharyngeal	B	2a	2	1	N	N
68008	Airway, Oropharyngeal, Anesthesiology	B	2a	2	1	N	N
68009	Algesimeter, Manual	A	1	1	1	N	N
68010	Algesimeter, Powered	B	2a	2	2	N	N
68011	Analyzer, Gas, Argon, Gaseous-Phase	C	2b	3	2	N	N
68012	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	C	2b	3	2	N	N
68013	Analyzer, Gas, Carbon-Dioxide, Partial Pressure, Blood-Phase, Indwelling	C	2b	3	2	N	N
68014	Analyzer, Gas, Carbon-Monoxide, Gaseous-Phase	C	2b	3	2	N	N
68015	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)	C	2b	3	2	N	N
68016	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)	C	2b	3	2	N	N
68017	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)	C	2b	3	2	N	N
68019	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)	C	2b	3	2	N	N
68020	Analyzer, Gas, Neon, Gaseous-Phase	C	2b	3	2	N	N
68021	Analyzer, Gas, Nitrogen, Gaseous-Phase	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68022	Analyzer, Gas, Nitrogen, Partial Pressure, Blood-Phase, Non-Indwelling	C	2b	3	3	N	N
68023	Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Conc.)	C	2b	3	2	N	N
68024	Analyzer, Gas, Oxygen, Gaseous-Phase	C	2b	3	2	N	N
68025	Analyzer, Gas, Oxygen, Partial Pressure, Blood-Phase, Indwelling	C	2b	3	2	N	N
68026	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)	C	2b	3	2	N	N
68027	Analyzer, Gas, Water Vapor, Gaseous-Phase	B	2a	2	1	N	N
68028	Analyzer, Hydrogen Gas	U	U	U	U	N	N
68029	Analyzer, Ion, Hydrogen-Ion (Ph), Blood-Phase, Indwelling	C	2b	3	2	N	N
68030	Analyzer, Nitric Oxide	C	2b	3	2	N	Y
68031	Analyzer, Nitrogen Dioxide	C	2b	3	2	N	Y
68032	Analyzer, Oxyhemoglobin Concentration, Blood-Phase, Indwelling	C	2b	3	3	N	N
68033	Anesthesia Breathing Circuit Kit (Adult & Pediatric)	D	3	2	1	N	N
68034	Anesthesia Conduction Kit	C	2b	3	2	N	N
68035	Anesthesia Kit	B	2a	2	2	N	N
68036	Apparatus, Autotransfusion	B	2a	2	2	N	Y
68037	Apparatus, Electronanesthesia	C	2b	3	3	N	N
68038	Apparatus, Gas-Scavenging	B	2a	2	2	N	N
68039	Apparatus, Nitric Oxide Delivery	C	2b	3	2	N	Y
68040	Apparatus, Nitric Oxide, Backup Delivery	C	2b	3	2	N	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68041	Applicator (Laryngo-Tracheal), Topical Anesthesia	B	2a	2	2	N	N
68042	Arterial Blood Sampling Kit	B	2a	2	1	N	N
68043	Attachment, Breathing, Positive End Expiratory Pressure	B	2a	2	2	N	Y
68044	Attachment, Intermittant Mandatory Ventilation (Imv)	B	2a	2	2	N	Y
68045	Bag, Reservoir	B	2a	2	1	N	N
68046	Bed, Rocking, Breathing Assist	C	2b	3	2	N	Y
68047	Blood Specimen Collection Kit (Excludes Hiv Testing)	B	2a	2	1	N	N
68048	Bottle, Blow	A	1	1	1	N	N
68049	Brachial Plexus Anesthesia Kit	B	2a	2	2	N	N
68050	Brush, Cleaning, Tracheal Tube	A	1	1	1	N	N
68051	Cabinet, Table And Tray, Anesthesia	A	1	1	1	N	N
68052	Calculator, Drug Dose	B	2a	2	2	N	N
68053	Calculator, Predicted Values, Pulmonary Function	B	2a	2	2	N	N
68054	Calculator, Pulmonary Function Data	B	2a	2	2	N	N
68055	Calculator, Pulmonary Function Interpretator (Diagnostic)	B	2a	2	2	N	N
68056	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	1	N	N
68057	Calibrator, Volume, Gas	B	2a	2	1	N	N
68058	Cannula, Nasal, Oxygen	B	2a	2	1	N	N
68059	Cardiopulmonary Resuscitation Aid Kit	D	3	1	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
868 ANESTHESIOLOGY DEVICES							
68060	Cart, Emergency, Cardiopulmonary (Excluding Equipment)	A	1	1	1	N	N
68061	Catheter, Conduction, Anesthetic	B	2a	2	2	N	N
68062	Catheter, Nasal, Oxygen	B	2a	2	1	N	N
68063	Catheters, Suction, Tracheobronchial	B	2a	2	1	N	N
68064	Caudal Anesthesia Kit	D	3	2	2	N	N
68065	Chair, Posture, For Cardiac And Pulmonary Treatment	A	1	1	1	N	N
68066	Chamber, Hyperbaric	C	2b	3	2	N	Y
68068	Circuit, Breathing (W Connector, Adaptor, Y Piece)	B	2a	2	1	N	N
68069	Circulator, Breathing-Circuit	B	2a	2	2	N	Y
68070	Clip, Nose	A	1	1	1	N	N
68071	Compressor, Air, Portable	B	2a	2	2	N	N
68072	Computer, Oxygen-Uptake	B	2a	2	2	N	N
68073	Condenser, Heat And Moisture (Artificial Nose)	B	2a	2	1	N	N
68074	Connector, Airway (Extension)	B	2a	2	1	N	N
68075	Conservator, Oxygen	C	2b	3	2	N	N
68076	Continuous Brachial Plexus Block Tray (Kit)	B	2a	2	2	N	N
68077	Continuous, Ventilator, Home Use	C	2b	3	2	N	Y
68077	Continuous, Ventilator, Home Use	C	2b	3	2	N	Y
68078	Cricothyrotomy Kit	B	2a	2	2	N	N
68079	Cuff, Tracheal Tube, Inflatable	B	2a	2	2	N	Y
68080	Custom Anesthesia Kit	B	3	2	2	N	N
68081	Cylinder, Compressed Gas, And Valve	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68082	Cylinder, Gas (Empty)	A	1	1	U	N	N
68083	Device, Fixation, Tracheal Tube	A	1	1	1	N	N
68084	Device, Positive Pressure Breathing, Intermittent	C	2b	3	2	N	N
68085	Device, Rebreathing	B	2a	2	1	N	N
68086	Device, Heimlich Maneuver Assist	D	3	1	2	N	Y
68087	Drain, Tee (Water Trap)	B	2a	2	1	N	N
68088	Dropper, Ether	A	1	1	1	N	N
68089	Epidural Anesthesia Kit	D	3	2	2	N	N
68090	Filter, Bacterial, Breathing-Circuit	D	3	2	2	N	N
68091	Filter, Conduction, Anesthetic	B	2a	2	2	N	N
68092	Flowmeter, Calibration, Gas	B	2a	2	1	N	N
68093	Flowmeter, Nonback-Pressure Compensated, Bourdon Gauge	B	2a	2	1	N	N
68094	Flowmeter, Tube, Thorpe, Back-Pressure Compensated	B	2a	2	1	N	N
68095	Forceps, Tube Introduction	B	2a	2	1	N	N
68096	Gas, Calibration (Specified Concentration)	B	2a	2	1	N	N
68097	Gas, Collecting Vessel	D	3	2	1	N	N
68098	Gas-Machine, Anesthesia	C	2b	3	2	N	Y
68099	Gauge, Gas Pressure, Cylinder/Pipeline	B	2a	2	1	N	N
68100	Generator, Oxygen, Portable	B	2a	2	2	N	Y
68101	Glossopharyngeal Anesthesia Kit	B	2a	2	2	N	N
68102	Heater, Breathing System W/Wo Controller (Not Humidifier Or Nebulizer)	B	2a	2	2	N	N
68103	Holding Chambers, Direct Patient Interface	B	3	2	2	N	N
68104	Hood, Oxygen, Infant	B	2a	2	1	N	N

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868 ANESTHESIOLOGY DEVICES							
68105	Hook, Ether	A	1	1	1	N	N
68106	Humidifier Nebulizer Kit	B	2a	2	2	N	N
68107	Humidifier, Non-Direct Patient Interface (Home-Use)	B	2a	2	1	N	N
68108	Humidifier, Respiratory Gas, (Direct Patient Interface)	B	2a	2	2	N	N
68109	Humidifier, Respiratory, Mask (Direct Patient Interface)	B	2a	2	2	N	N
68110	Kit, Tracheostomy And Nasal Suctioning	B	2a	2	U	N	N
68111	Kit, Tracheotomy Care	B	2a	2	2	N	N
68112	Laryngoscope Kit	B	2a	2	1	N	N
68113	Laryngoscope, Non-Rigid	B	2a	2	1	N	N
68114	Laryngoscope, Rigid	B	2a	2	1	N	N
68115	Mask, Gas, Anesthetic	B	2a	2	1	N	N
68116	Mask, Oxygen	B	2a	2	1	N	N
68117	Mask, Oxygen, Low Concentration, Venturi	B	2a	2	1	N	N
68118	Mask, Oxygen, Non-Rebreathing	B	2a	2	1	N	N
68119	Mask, Scavenging	B	2a	2	1	N	N
68120	Mask, Ventilator, Non-Continuous, Reprocessed	B	2a	2	2	N	N
68121	Mechanical Ventilator	B	2a	2	2	N	N
68122	Medevac Use Oxygen Generator	B	2a	2	2	N	N
68123	Membrane, Lung, (For Long-Term Respiratory Support)	C	2b	3	3	N	Y
68124	Meter, Airway Pressure (Inspiratory Force)	B	2a	2	2	N	N
68125	Meter, Peak Flow, Spirometry	B	2a	2	2	N	N

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868 ANESTHESIOLOGY DEVICES							
68126	Mixer, Breathing Gases, Anesthesia Inhalation	B	2a	2	2	N	Y
68127	Monitor, Air Embolism, Ultrasonic	C	2b	3	2	N	N
68128	Monitor, Airway Pressure (Includes Gauge And/Or Alarm)	C	2b	3	2	N	N
68129	Monitor, Apnea, Facility Use	B	2a	2	2	N	Y
68130	Monitor, Apnea, Home Use	B	2a	2	2	N	Y
68131	Monitor, Breathing Frequency	B	2a	2	2	N	N
68132	Monitor, Carbon-Dioxide, Cutaneous	C	2b	3	2	N	N
68133	Monitor, Lung Water Measurement	C	2b	3	3	N	N
68134	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia	C	2b	3	2	N	N
68135	Monitor, Oxygen, Cutaneous, For Uses Other Than For Infant Not Under Gas Anesthesia	C	2b	3	2	N	N
68136	Monitor, Pressure, Intracompartmental	C	2b	3	U	N	N
68137	Mouthpiece, Breathing	B	2a	2	1	N	N
68138	Nasal Endotracheal Tube Holder Kit	A	1	1	1	N	N
68139	Nebulizer (Direct Patient Interface)	B	2a	2	2	N	N
68140	Nebulizer, Medicinal, Non-Ventilatory (Atomizer)	B	2a	2	1	N	N
68141	Needle, Conduction, Anesthesia, Reprocessed	B	2a	2	2	N	N
68142	Needle, Conduction, Anesthetic (W/Wo Introducer)	D	3	2	2	N	N
68143	Needle, Emergency Airway	B	2a	2	2	N	Y
68144	Needle, Spinal, Short Term	B	2a	2	2	N	N
68145	Needle, Spinal, Short Term, Reprocessed	B	2a	2	2	N	N
68146	Nerve Block Tray (Kit)	B	2a	2	2	N	N

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868 ANESTHESIOLOGY DEVICES							
68147	Non-Bronchoscopic Bronchoalveolar Lavage Catheter	B	2a	2	1	N	N
68148	Orotracheal Intubation Guide Kit	B	2a	2	2	N	N
68149	Oxygen Administration Kit	B	2a	2	2	N	N
68150	Percussor, Powered-Electric	B	2a	2	2	N	N
68151	Plethysmograph, Pressure	B	2a	2	2	N	N
68152	Plethysmograph, Volume	B	2a	2	2	N	N
68153	Pneumotachometer	B	2a	2	2	N	N
68154	Protector, Dental	A	1	1	1	N	N
68155	Regional Anesthesia Kit	B	2a	2	2	N	N
68156	Regulator, Pressure, Gas Cylinder	B	2a	2	1	N	N
68157	Resuscitator, Manual, Non Self-Inflating	B	2a	2	2	N	Y
68158	Rhinoanemometer (Measurement Of Nasal Decongestion)	B	2a	2	2	N	N
68159	Set, Tubing And Support, Ventilator (W Harness)	B	2a	2	1	N	N
68160	Spacer, Direct Patient Interface	B	2a	2	2	N	N
68161	Spinal Anesthesia Kit	B	2a	2	2	N	N
68162	Spinal Epidural Anesthesia Kit	B	2a	2	2	N	N
68163	Spirometer, Diagnostic	B	2a	2	2	N	N
68164	Spirometer, Monitoring (W/Wo Alarm)	B	2a	2	2	N	N
68165	Spirometer, Therapeutic (Incentive)	B	2a	2	2	N	N
68166	Spreader, Cuff	A	1	1	1	N	N
68167	Stethoscope Head	A	1	1	1	N	N
68168	Stethoscope, Esophageal	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68169	Stethoscope, Esophageal, With Electrical Conductors	B	2a	2	2	N	N
68170	Stimulator, Nerve, Ac-Powered	B	3	2	2	N	N
68171	Stimulator, Nerve, Battery-Powered	B	3	2	2	N	N
68172	Stimulator, Nerve, Peripheral, Electric	B	3	2	2	N	N
68173	Stool, Anesthesia	U	3	U	1	N	N
68174	Strap, Head, Gas Mask	A	3	1	1	N	N
68175	Stylet, Tracheal Tube	B	3	2	1	N	N
68176	Support, Breathing Tube	A	3	1	1	N	N
68177	Support, Patient Position	A	3	1	1	N	N
68178	Tent, Oxygen	B	3	2	1	N	N
68179	Tent, Oxygen, Electrically Powered	B	3	2	2	N	Y
68180	Tent, Pediatric Aerosol	B	2a	2	2	N	N
68181	Tracheal Suction Set (Kit)	B	3	2	1	N	N
68182	Tracheobronchial Suction Catheter Kit	B	3	2	1	N	N
68183	Tracheostomy Cleaning Tray	B	3	2	2	N	N
68184	Tracheostomy Kit	B	3	2	2	N	N
68185	Transducer, Gas Flow	B	3	2	1	N	N
68186	Transducer, Gas Pressure	B	3	2	1	N	N
68187	Transducer, Gas Pressure, Differential	B	3	2	1	N	N
68188	Tube Tracheostomy And Tube Cuff	D	3	2	2	N	Y
68189	Tube, Bronchial (W/Wo Connector)	B	3	2	2	N	Y
68190	Tube, Thorpe, Uncompensated	B	3	2	1	N	N
68191	Tube, Tracheal (W/Wo Connector)	B	3	2	2	N	Y
68192	Tube, Tracheal, Reprocessed	B	3	2	2	N	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
868 ANESTHESIOLOGY DEVICES							
68193	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	B	3	2	2	N	Y
68194	Tube, Tracheostomy (W/Wo Connector)	B	3	2	2	N	Y
68195	Tubing, Pressure And Accessories	B	2a	2	1	N	N
68196	Unit, Liquid-Oxygen, Portable	B	2a	2	2	N	N
68197	Valve, Non-Rebreathing	B	2a	2	2	N	Y
68198	Valve, Switching (Ploss)	B	2a	2	1	N	N
68199	Vaporizer, Anesthesia, Non-Heated	C	3	3	2	N	N
68200	Ventilator, Continuous, Facility Use	C	2b	3	2	N	Y
68201	Ventilator, Continuous, Minimal Ventilatory Support, Home Use	C	2b	3	2	N	Y
68202	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	C	2b	3	2	N	Y
68203	Ventilator, Continuous, Non-Life-Supporting	C	2b	3	2	N	N
68204	Ventilator, Emergency, Manual (Resuscitator)	B	2a	2	2	N	Y
68205	Ventilator, Emergency, Powered (Resuscitator)	C	2b	3	2	N	Y
68206	Ventilator, External Body, Negative Pressure, Adult (Cuirass)	C	2b	3	2	N	Y
68207	Ventilator, High Frequency	C	2b	3	3	N	N
68208	Ventilator, Non-Continuous (Respirator)	C	2b	3	2	N	N
68209	Ventilatory Effort Recorder	B	2a	2	2	N	N
68210	Yoke Assembly, Medical Gas	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70001	Accessory Equipment, Cardiopulmonary Bypass	B	2a	2	1	N	N
70002	Actuator, Syringe, For Injector, Reprocessed	C	2b	3	2	N	N
70003	Actuator, Syringe, Injector Type	C	2b	3	2	N	N
70004	Adaptor, Lead Switching, Electrocardiograph	B	2a	2	2	N	N
70005	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass	B	2a	2	2	N	N
70006	Agent, Injectable, Embolic	D	3	4	3	N	N
70007	Agents, Embolic, For Treatment Of Uterine Fibroids	C	2b	3	2	Y	N
70008	Aid, Cardiopulmonary Resuscitation	A	1	1	3	N	N
70009	Alarm, Blood-Pressure	C	2b	3	2	N	N
70010	Alarm, Leakage Current, Portable	B	2a	2	1	N	N
70011	Amplifier And Signal Conditioner, Biopotential	B	2a	2	2	N	N
70012	Amplifier And Signal Conditioner, Transducer Signal	B	2a	2	2	N	N
70013	Analyzer, Body Composition	B	2a	2	2	N	N
70014	Analyzer, Pacemaker Generator Function	B	2a	2	2	N	N
70015	Analyzer, Pacemaker Generator Function, Indirect	C	2b	3	2	N	N
70016	Angiography/Angioplasty Kit	D	3	4	2	N	N
70017	Angioscopic Valvulotome Kit	C	2b	3	2	N	N
70018	Antimicrobial Blood Pressure Cuff	B	2a	2	2	N	N
70019	Aortic Heart Valve, More Than Minimally Manipulated Allograft	D	3	4	3	Y	Y
70020	Aortic Valve, Prosthesis, Percutaneously Delivered	D	3	4	3	Y	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70021	Apparatus, Suction, Patient Care	B	2a	2	2	N	N
70022	Artificial Heart	D	3	4	3	Y	N
70023	Atrial Defibrillator	C	2b	3	3	Y	Y
70024	Automated External Defibrillators (Non-Wearable)	D	3	4	3	N	N
70025	Auxillary Power Supply (Ac Or Dc) For External Transcutaneous Cardiac Pacemaker	B	2a	2	2	N	Y
70026	Auxillary Power Supply (Ac Or Dc) For Low-Energy Dc-Defibrillator	B	2a	2	2	N	Y
70027	Bag, Polymeric Mesh, Pacemaker	C	2b	3	1	Y	N
70028	Ballistocardiograph	B	2a	2	2	N	N
70029	Balloon Aortic Valvuloplasty	C	2b	3	2	N	N
70030	Barrier, Adhesion, Cardiovascular	D	3	4	3	Y	N
70031	Batteries, Rechargeable, For Class 2 Devices	B	2a	2	U	N	N
70032	Batteries, Rechargeable, For Class 3 Devices	D	3	4	U	N	N
70033	Blood Pressure Cuff	B	2a	2	2	N	N
70034	Cable, Transducer And Electrode, Patient, (Including Connector)	B	2a	2	2	N	N
70035	Cadriovascular Catheter Sheath Introducer Kit	D	3	4	2	N	N
70036	Cannula, Arterial, Cardiopulmonary Bypass (Cpb), Embolism Protection	B	2a	2	2	N	N
70037	Cannula, Catheter	B	2a	2	2	N	N
70038	Cardiac Ablation Percutaneous Catheter	D	3	4	3	N	N
70039	Cardiac Catheterization Kit	D	3	4	2	N	N
70040	Cardiac Support Mesh Wrap	D	3	4	U	Y	N
70041	Cardiograph, Apex (Vibrocardiograph)	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70042	Cardioplegia Solution Administration Kit	B	2a	2	2	N	N
70043	Cardiopulmonary Bypass Catheter Kit	D	3	4	2	N	N
70044	Cardiovascular Procedure Kit	B	2a	2	2	N	N
70045	Cardiovascular Surgical Instruments Tray (Kit)	B	2a	2	1	N	N
70046	Catheter Guide Wire Kit	B	2a	2	2	N	N
70047	Catheter Introducer Kit	B	2a	2	2	N	N
70048	Catheter, Angiography, Reprocessed	B	2a	2	2	N	N
70153	Catheter, Angioplasty, Peripheral, Transluminal	D	3	4	U		zz
70050	Catheter, Angioplasty, Peripheral, Transluminal, Dual-Balloon	D	3	4	2	N	N
70051	Catheter, Angioplasty, Peripheral, Transluminal, Reprocessed	C	2b	3	U	N	N
70052	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass	B	2a	2	2	N	N
70053	Catheter, Continuous Flush	B	2a	2	2	N	N
70054	Catheter, Coronary, Atherectomy	D	3	4	3	N	N
70055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	D	3	4	2	N	N
70056	Catheter, Embolectomy	D	3	4	2	N	N
70057	Catheter, Flow Directed	D	3	4	2	N	N
70058	Catheter, Intravascular Occluding, Temporary	D	3	2	2	N	N
70059	Catheter, Intravascular, Diagnostic	D	3	4	2	N	N
70060	Catheter, Intravascular, Plaque Morphology Evaluation	D	3	4	2	N	N
70061	Catheter, Mapping, Intracardiac, Reprocessed	D	3	4	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
870 CARDIOVASCULAR DEVICES							
70062	Catheter, Oximeter, Fiber Optic, Reprocessed	D	3	4	2	N	N
70063	Catheter, Oximeter, Fiberoptic	D	3	4	2	N	N
70064	Catheter, Percutaneous	D	3	4	2	N	N
70065	Catheter, Percutaneous (Valvuloplasty)	D	3	4	3	N	N
70066	Catheter, Percutaneous Transluminal Coronary Angioplasty (Ptca), Cutting/Scoring	D	3	4	3	N	N
70067	Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Fibrillation	D	3	4	3	N	Y
70068	Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Flutter	D	3	4	3	N	Y
70069	Catheter, Peripheral, Atherectomy	D	3	4	2	N	N
70070	Catheter, Pressure Monitoring, Cardiac	D	3	4	2	N	N
70071	Catheter, Recording, Electrode, Reprocessed	D	3	4	2	N	N
70072	Catheter, Septostomy	D	3	4	2	N	N
70073	Catheter, Steerable	D	3	4	2	N	N
70074	Catheter, Steerable, Reprocessed	D	3	4	2	N	N
70075	Catheter, Thrombus Retriever	D	3	4	2	N	N
70076	Catheter, Ultrasound, Intravascular	D	3	4	2	N	N
70077	Catheter, Intracardiac Mapping, High-Density Array	D	3	4	2	N	N
70078	Catheters, Transluminal Coronary Angioplasty, Percutaneous	D	3	4	2	N	N
70079	Central Venous Blood Pressure Kit	D	3	4	2	N	N
70080	Central Venous Catheter Tray (Kit)	D	3	4	2	N	N
70081	Charger, Pacemaker	B	2a	2	1	N	N
70082	Clamp, Vascular	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
870 CARDIOVASCULAR DEVICES							
70083	Clamp, Vascular, Reprocessed	B	2a	2	2	N	N
70084	Clip, Vascular	D	3	4	2	Y	N
70085	Clip, Vena-Cava	D	3	4	2	Y	N
70086	Compressor, Cardiac, External	D	3	4	3	N	N
70087	Computer, Blood-Pressure	C	2b	3	2	N	N
70088	Computer, Diagnostic, Pre-Programmed, Single-Function	D	3	2	2	N	N
70089	Computer, Diagnostic, Programmable	D	3	2	2	N	N
70090	Console, Heart-Lung Machine, Cardiopulmonary Bypass	C	2b	3	2	N	Y
70091	Control, Pump Speed, Cardiopulmonary Bypass	B	2a	2	2	N	Y
70092	Controller, Closed-Loop, Blood-Pressure	D	3	4	3	N	N
70093	Controller, Temperature, Cardiopulmonary Bypass	B	2a	2	2	N	Y
70094	Coronary Covered Stent	D	3	4	U	Y	Y
70095	Coronary Drug-Eluting Stent	D	3	4	U	Y	Y
70096	Cpb Check Valve, Retrograde Flow, In-Line	D	3	2	2	N	N
70097	Ct Biopsy Tray (Kit)	B	2a	2	2	N	N
70098	Dc-Defibrillator, High Energy, (Including Paddles)	C	2b	3	3	N	N
70099	Dc-Defibrillator, Low-Energy, (Including Paddles)	C	2b	3	2	N	Y
70100	Defibrillator, Automatic Implantable Cardioverter, With Cardiac Resynchronization (Crt-D)	D	3	4	3	Y	Y
70101	Defibrillator, Implantable, Dual-Chamber	D	3	4	3	Y	Y
70102	Defoamer, Cardiopulmonary Bypass	B	3	2	2	N	Y
70103	Densitometer	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70104	Detector And Alarm, Arrhythmia	C	2b	3	2	N	N
70105	Detector, Bubble, Cardiopulmonary Bypass	C	2b	3	2	N	N
70107	Device, Angioplasty, Laser, Coronary	D	3	4	3	N	N
70108	Device, Biopsy, Endomyocardial	B	2a	2	2	N	N
70109	Device, Counter-Pulsating, External	B	2a	2	3	N	N
70110	Device, Hemostasis, Vascular	D	3	4	3	N	N
70111	Device, Percutaneous Retrieval	B	2a	2	2	N	N
70112	Device, Removal, Pacemaker Electrode, Percutaneous	D	3	4	3	N	N
70113	Device, Vascular, For Promoting Embolization	D	3	4	2	Y	N
70114	Device, Anastomotic, Microvascular	B	2a	2	U	N	N
70115	Device, Laser Peripheral Angioplasty	D	3	4	3	N	N
70116	Digital Angiography Tray (Kit)	B	2a	2	2	N	N
70117	Dilator, Vessel, For Percutaneous Catheterization	B	2a	2	2	N	N
70118	Dilator, Vessel, Surgical	B	2a	2	2	N	N
70119	Display, Cathode-Ray Tube, Medical	B	2a	2	2	N	N
70120	Drug Eluting Permanent Left Ventricular (Lv) Pacemaker Electrode	D	3	4	3	Y	Y
70121	Drug Eluting Permanent Right Ventricular (Rv) Or Right Atrial (Ra) Pacemaker Electrodes	D	3	4	3	Y	Y
70122	Echocardiograph	B	2a	2	2	N	N
70124	Electrocardiograph	B	2a	2	2	N	N
70125	Electrocardiograph, Ambulatory, With Analysis Algorithm	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70126	Electrocardiograph,Ambulatory(Without Analysis)	B	2a	2	2	N	N
70127	Electrode, Electrocardiograph	B	2a	2	2	N	N
70128	Electrode, Electrocardiograph, Multi-Function	B	2a	2	2	N	N
70129	Electrode, Pacemaker, Temporary	D	3	4	2	N	Y
70130	Electrode, Pacing And Cardioversion, Temporary, Epicardial	D	3	4	2	N	Y
70131	Endovascular Suturing System	D	3	4	2	Y	N
70132	Fibrillator, Ac	D	3	4	2		zz
70133	Filter, Blood, Cardiopulmonary Bypass, Arterial Line	B	2a	2	2	N	Y
70134	Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	B	2a	2	2	N	N
70135	Filter, Intravascular, Cardiovascular	D	3	4	2	Y	N
70136	Filter, Prebypass, Cardiopulmonary Bypass	B	2a	2	2	N	N
70137	Flowmeter, Blood, Cardiovascular	B	2a	2	2	N	N
70138	Gas Control Unit, Cardiopulmonary Bypass	B	2a	2	2	N	Y
70139	Gauge, Pressure, Coronary, Cardiopulmonary Bypass	C	2b	3	2	N	N
70140	Generator, Pulsatile Flow, Cardiopulmonary Bypass	C	2b	3	3	N	N
70141	Generator, Pulse, Pacemaker, External Programmable	D	3	4	2	N	Y
70142	Glue,Surgical,Arteries	D	3	4	3	Y	Y
70143	Graft, Vascular, Synthetic/Biologic Composite	D	3	4	2	Y	N
70144	Graft,Bypass,Coronary Artery	D	3	4	U	Y	Y

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870 CARDIOVASCULAR DEVICES							
70145	Graft,Vascular,Stainless Steel Tunneler	D	3	4	2	N	N
70146	Guide, Wire, Catheter, Neurovasculature	B	2a	2	2	N	N
70147	Guidewire, Catheter, Reprocessed	B	2a	2	2	N	N
70148	Heart Valve, More Than Minimally Manipulated Allograft	D	3	4	U	Y	N
70149	Heart-Valve, Allograft	D	3	4	3	Y	N
70150	Heart-Valve, Mechanical	D	3	4	3	Y	Y
70151	Heart-Valve, Non-Allograft Tissue	D	3	4	3	Y	N
70152	Heat-Exchanger, Cardiopulmonary Bypass	B	2a	2	2	N	Y
70154	Holder, Heart-Valve, Prosthesis	B	2a	2	1	N	N
70155	Hyperthermia Monitor	C	2b	3	2	N	N
70156	Implantable Cardioverter Defibrillator (Non-Crt)	D	3	4	3	Y	Y
70157	Implantable Pacemaker Pulse-Generator	D	3	4	3	Y	N
70158	Implantable Pulse Generator, Pacemaker (Non-Crt)	D	3	4	3	Y	Y
70159	Injector And Syringe, Angiographic	B	2a	2	2	N	N
70160	Injector And Syringe, Angiographic, Balloon Inflation, Reprocessed	B	2a	2	2	N	N
70161	Injector And Syringe, Angiographic, Reprocessed	B	2a	2	2	N	N
70162	Injector, Contrast Medium, Automatic	C	2b	3	2	N	N
70163	Injector, Contrast Medium, Automatic, Reprocessed	D	3	4	2	N	N
70164	Injector, Indicator	B	2a	2	2	N	N
70165	Instruments, Surgical, Cardiovascular	B	2a	2	1	N	N
70166	Intravascular Radiation Delivery System	D	3	4	3	N	N
70167	Introducer, Catheter	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
870 CARDIOVASCULAR DEVICES							
70168	Kit, Balloon Repair, Catheter	D	3	4	3	N	N
70169	Kit, Cell Harvesting, Endothelial	D	3	4	2	N	N
70170	Laser Blood Flow Kit	C	2b	3	2	N	N
70171	Lead Introducer Kit	B	2a	2	2	N	N
70172	Legging, Compression, Non-Inflatable	A	3	1	U	N	N
70173	Lung Sound Monitor	B	3	2	2	N	N
70174	Magnet, Test, Pacemaker	B	3	2	1	N	N
70175	Manometer, Blood-Pressure, Venous	B	3	2	2	N	N
70176	Marker, Cardiopulmonary Bypass (Vein Marker)	D	3	4	U	N	N
70177	Material, Embolization, Neurovascular, Polymerizing Or Precipitating	D	3	4	3	N	Y
70178	Materials, Repair Or Replacement, Pacemaker	D	3	4	3	Y	N
70179	Microsphere, Trace	C	3	3	3	Y	N
70180	Monitor And/Or Control, Level Sensing, Cardiopulmonary Bypass	C	3	3	2	N	N
70181	Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass	C	3	3	2	N	N
70182	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	C	2b	3	2	N	N
70183	Monitor, Extracellular Fluid, Lymphedema, Extremity	B	3	2	2	N	N
70184	Monitor, Line Isolation	A	3	1	1	N	N
70187	Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)	C	3	3	2	N	N
70185	Monitor, St Segment	B	3	2	2	N	N
70186	Monitor, St Segment With Alarm	B	3	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70188	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	C	3	3	2	N	N
70189	Occluder, Balloon, Vena-Cava	D	3	4	3	N	N
70190	Occluder, Catheter Tip	D	3	2	2	N	N
70191	Occluder, Internal Vessel, Temporary	C	3	3	3	N	N
70192	Occluder, Patent Ductus, Arteriosus	D	3	4	3	Y	N
70193	Optical Coherence Tomography, Intravascular Catheter	C	3	3	2	N	N
70194	Oscillometer	B	3	2	2	N	N
70196	Over-The-Counter Automated External Defibrillator	C	3	3	3	N	Y
70197	Oximeter	C	3	3	2	N	N
70198	Oximeter, Ear	C	2b	3	2	N	N
70199	Oximeter, Infrared, Sporting, Aviation	C	2b	3	2	N	N
70200	Oximeter, Reprocessed	C	2b	3	2	N	N
70202	Oximeter, Tissue Saturation, Reprocessed	C	2b	3	2	N	N
70203	Oxygenator, Cardiopulmonary Bypass	C	3	3	2	N	Y
70204	Pacemaker Battery	D	3	4	3	Y	N
70205	Pacemaker Lead Adaptor	D	3	4	2	Y	N
70206	Pacemaker, Cardiac, External Transcutaneous (Non-Invasive)	C	2b	3	2	N	Y
70207	Pacemaker/Icd/Crt Non-Implanted Components	D	3	4	3	Y	N
70208	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene	D	3	4	2	Y	N
70209	Percutaneous Atrial Catheter Kit	D	3	4	2	N	N
70210	Percutaneous Sheath Introducer Kit	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
870 CARDIOVASCULAR DEVICES							
70211	Pericardial Patch To Facilitate Revision Surgeries	D	3	4	2	Y	Y
70212	Permanent Defibrillator Electrodes	D	3	4	3	Y	Y
70213	Permanent Pacemaker Electrode	D	3	4	3	Y	N
70214	Phlebograph, Impedance	B	2a	2	2	N	N
70215	Phlebotomy Blood Collection Kit	B	2a	2	2	N	N
70216	Phonocardiograph	B	2a	2	1	N	N
70217	Plethysmograph, Air Displacement For Body Composition Analysis	B	2a	2	2	N	N
70218	Plethysmograph, Impedance	B	2a	2	2	N	N
70219	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic	B	2a	2	2	N	N
70220	Polymerizing, Neurovascular Embolization Material	D	3	4	f	Y	Y
70221	Probe, Blood-Flow, Extravascular	C	2b	3	2	N	N
70222	Probe, Test, Heart-Valve	B	2a	2	1	N	N
70223	Probe, Thermodilution	D	3	4	2	N	N
70224	Programmer, Pacemaker	D	3	4	3	N	N
70225	Prosthesis, Arterial Graft, Bovine Carotid Artery	D	3	4	3	N	N
70226	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	D	3	4	2	Y	N
70227	Prosthesis, Vascular Graft, Of Less Than 6mm Diameter	D	3	4	2	Y	N
70228	Pulmonary (Pulmonic) Valvuloplasty Catheters/Percutaneous Valvuloplasty Catheter	C	2b	3	2	N	N
70229	Pulmonary Valve Prosthesis Percutaneously Delivered	D	3	4	U	Y	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70230	Pulmonic Replacement Heart Valve	D	3	4	U	Y	Y
70231	Pulmonic Valved Conduit	D	3	4	U	Y	Y
70232	Pulse Generator, External Pacemaker, Dual-Chamber	D	3	4	3	N	Y
70233	Pulse Generator, Pacemaker, Implantable, With Cardiac Resynchronization (Crt-P)	D	3	4	3	Y	Y
70234	Pulse Generator, Permanent, Implantable	D	3	4	3	Y	Y
70235	Pulse-Generator, Pacemaker, External	D	3	4	3	N	N
70283	Pulse-Generator, Program Module	C	2b	3	U		zz
70237	Pulse-Generator, Single Chamber, Sensor Driven, Implantable	D	3	4	3	Y	N
70238	Pulse-Generator, Single Chamber, Single	D	3	4	3	N	N
70239	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type	C	2b	3	3	N	N
70240	Pump, Blood, Cardiopulmonary Bypass, Roller Type	B	2a	2	2	N	Y
70241	Recorder, Magnetic Tape, Medical	A	1	1	2	N	N
70242	Recorder, Paper Chart	B	2a	2	1	N	N
70243	Recorder,Event,Implantable Cardiac,(With Arrhythmia Detection)	D	3	4	2	Y	N
70244	Recorder,Event,Implantable Cardiac,(Without Arrhythmia Detection)	D	3	4	2	Y	N
70245	Replacement Heart-Valve	D	3	4	3	Y	N
70246	Reprocessed Blood Pressure Cuff	B	2a	2	2	N	N
70247	Reprocessed Intravascular Ultrasound Catheter	D	3	4	2	N	N
70248	Reservoir, Blood, Cardiopulmonary Bypass	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70249	Right Ventricular Bypass (Assist) Device	D	3	4	U	N	N
70250	Ring, Annuloplasty	D	3	4	2	Y	N
70251	Rotator, Prosthetic Heart Valve	D	3	4	U	Y	Y
70252	Sensor, Blood-Gas, In-Line, Cardiopulmonary Bypass	B	2a	2	2	N	N
70253	Sensor, Pressure, Aneurysm, Implantable	D	3	4	2	Y	N
70254	Shunt, Portosystemic, Endoprosthesis	D	3	4	3	Y	N
70255	Single Lead Over-The-Counter Electrocardiograph	B	2a	2	2	N	N
70256	Sizer, Heart-Valve, Prosthesis	B	2a	2	1	N	N
70257	Sleeve, Limb, Compressible	B	2a	2	2	N	N
70258	Stabilizer, Heart, Non-Compression, Reprocessed	B	2a	2	1	N	N
70259	Stabilizer,Heart	D	2a	2	1	N	N
70260	Stent, Carotid	D	3	4	3	Y	Y
70261	Stent, Coronary	D	3	4	3	Y	N
70262	Stent, Iliac	D	3	4	3	Y	Y
70263	Stent, Renal	D	3	4	3	Y	Y
70264	Stent, Superficial Femoral Artery	D	3	4	3	Y	Y
70265	Stethoscope, Electronic	D	2a	2	2	N	N
70266	Stethoscope, Manual	D	1	1	1	N	N
70267	Stimulator, Carotid Sinus Nerve	C	2b	3	3	Y	N
70268	Stripper, Artery, Intraluminal	A	1	1	2	N	N
70269	Stripper, Vein, External	A	1	1	2	N	N
70270	Stripper, Vein, External, Reprocessed	A	1	1	2	N	N
70271	Stylet, Catheter	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70272	Sucker, Cardiotomy Return, Cardiopulmonary Bypass	B	2a	2	2	N	N
70273	Suction Control, Intracardiac, Cardiopulmonary Bypass	B	2a	2	2	N	N
70274	Surgical Cardiac Ablation Device, For Treatment Of Atrial Fibrillation	D	3	4	3	N	N
70275	Suture, Cardiovascular	D	3	4	3	Y	N
70276	Syringe, Balloon Inflation	B	2a	2	2	N	N
70277	System, Appendage Closure, Left Atrial	D	3	4	U	Y	N
70278	System, Balloon, Intra-Aortic And Control	D	3	4	3	N	N
70279	System, Balloon, Intra-Aortic And Control, Reprocessed	D	3	4	3	N	N
70280	System, Catheter Control, Reprocessed	C	2b	3	2	N	N
70281	System, Catheter Control, Steerable	C	2b	3	2	N	N
70282	System, Catheter Or Guidewire, Steerable (Magnetic)	D	3	4	2	N	N
70284	System, Endovascular Graft, Aortic Aneurysm Treatment	D	3	4	3	Y	N
70285	System, Esophageal Pacing	D	3	4	3	N	N
70286	System, Hypothermia, Intravenous, Cooling	B	2a	2	2	N	N
70287	System, Laser, Transmyocardial Revascularization	D	3	4	3	N	N
70288	System, Measurement, Blood-Pressure, Non-Invasive	B	2a	2	2	N	N
70289	System, Phonocatheter, Intracavitary	C	2b	3	2	N	N
70290	System, Signal Isolation	A	1	1	1	N	N
70291	System, Thermal Regulating	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
870 CARDIOVASCULAR DEVICES							
70292	System,Network And Communication,Physiological Monitors	B	2a	2	2	N	Y
70293	System,Pacing,Temporary,Acute,Internal Atrial Defibrillation	D	3	4	3	N	Y
70294	Temporary Carotid Catheter For Embolic Capture	D	3	4	2	N	N
70295	Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection	D	3	4	2	N	N
70296	Tester, Defibrillator	B	2a	2	2	N	N
70297	Tester, Electrode, Surface, Electrocardiographic	B	2a	2	2	N	N
70298	Tester, Pacemaker Electrode Function	B	2a	2	2	N	N
70299	Tissue Adhesive, Aortic Aneurysmorrhaphy	D	3	4	U	Y	N
70300	Tissue Graft Of 6mm And Greater	D	3	4	3	N	N
70301	Tissue Graft Of Less Than 6mm	D	3	4	3	N	N
70302	Tools, Pacemaker Service	A	1	1	1	N	N
70303	Tourniquet, Automatic Rotating	C	2b	3	2	N	N
70304	Transcatheter Septal Occluder	D	3	4	3	N	Y
70305	Transcatheter Septal Occluder (Atrial)	D	3	4	3	Y	N
70306	Transcatheter Septal Occluder (Ventricular)	D	3	4	3	Y	N
70307	Transducer, Apex Cardiographic	B	2a	2	2	N	N
70308	Transducer, Blood-Pressure, Extravascular	B	2a	2	2	N	N
70309	Transducer, Heart Sound	B	2a	2	2	N	N
70310	Transducer, Pressure, Catheter Tip	D	3	4	2	N	N
70311	Transducer, Ultrasonic	C	2b	3	2	N	N
70312	Transducer, Vessel Occlusion	D	3	4	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
870 CARDIOVASCULAR DEVICES							
70313	Transmitters And Receivers, Electrocardiograph, Telephone	B	2a	2	2	N	N
70314	Transmitters And Receivers, Physiological Signal, Radiofrequency	B	2a	2	2	N	N
70315	Trocar	B	2a	2	2	N	N
70316	Trocar, Reprocessed	B	2a	2	2	N	N
70317	Tubing, Pump, Cardiopulmonary Bypass	B	2a	2	2	N	N
70318	Ultrasonic Body Composition Analyzer	B	2a	2	2	N	N
70319	Ultrasound, Infusion, System	B	2a	2	2	N	N
70320	Valve, Pressure Relief, Cardiopulmonary Bypass	B	2a	2	U	N	N
70321	Valvulotome	B	2a	2	2	N	N
70322	Vectorcardiograph	B	2a	2	2	N	N
70323	Ventricular (Assist) Bypass	D	3	4	3	Y	N
70324	Ventricular Bypass (Assist) Device	D	3	4	3	N	N
70325	Vessel Guard Or Cover	B	2a	2	2	Y	N
70326	Vessel Guard Or Cover, To Facilitate Revision Surgeries	B	2a	2	2	N	N
70327	Wearable Automated External Defibrillator	D	3	4	3	N	Y
70328	Winged Intravenous Catheterization Kit	B	2a	2	2	N	N
70329	Wire, Guide, Catheter	B	2a	2	2	N	N
70330	Withdrawal/Infusion Pump	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72001	Absorber, Saliva, Paper	A	1	1	1	N	N
72002	Abutment, Implant, Dental, Endosseous	C	2b	3	2	Y	N
72003	Accessories, Implant, Dental, Endosseous	A	1	3	1	N	N
72004	Accessories, Retractor, Dental	A	1	1	1	N	N
72005	Activator, Ultraviolet, For Polymerization	A	1	1	2	N	N
72006	Adhesive, Bracket And Tooth Conditioner, Resin	B	2a	2	2	N	N
72007	Adhesive, Denture, Acacia And Karaya With Sodium Borate	A	1	2	1	N	N
72008	Adhesive, Denture, Acacia And Karaya With Sodium Borate > 12% By Weight	D	3	3	3	N	N
72009	Adhesive, Denture, Carboxymethylcellulose Sodium (32%) And Ethylene-Oxide Homopolymer	A	1	2	1	N	N
72010	Adhesive, Denture, Carboxymethylcellulose Sodium (40-100%)	A	1	2	1	N	N
72011	Adhesive, Denture, Carboxymethylcellulose Sodium (49%) And Ethylene-Oxide Homopolymer	A	1	2	1	N	N
72012	Adhesive, Denture, Carboxymethylcellulose Sodium And Cationic Polyacrylamide Polymer	A	1	3	3	N	N
72013	Adhesive, Denture, Karaya	A	1	2	1	N	N
72014	Adhesive, Denture, Karaya And Ethylene-Oxide Homopolymer	A	1	2	1	N	N
72015	Adhesive, Denture, Karaya With Sodium Borate	D	3	3	3	N	N
72016	Adhesive, Denture, Polyacrylamide Polymer (Modified Cationic)	A	1	3	3	N	N
72017	Adhesive, Denture, Polyvinyl Methylether Maleic Acid Calcium-Sodium Double Salt	A	1	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
872 DENTAL DEVICES							
72018	Agent, Polishing, Abrasive, Oral Cavity	A	1	1	1	N	N
72019	Agent, Tooth Bonding, Resin	B	2a	3	2	N	N
72020	Airbrush	B	2a	2	2	N	N
72021	Aligner, Beam, X-Ray	A	1	1	1	N	N
72022	Aligner, Bracket, Orthodontic	A	1	1	1	N	N
72023	Aligner, Sequential	B	2a	2	2	N	N
72024	Alloy, Amalgam	B	2a	3	2	N	N
72025	Alloy, Gold-Based Noble Metal	B	2a	3	2	N	N
72026	Alloy, Metal, Base	B	2a	3	2	N	N
72027	Alloy, Other Noble Metal	B	2a	3	2	N	N
72028	Amalgamator, Dental, Ac-Powered	A	1	1	1	N	N
72029	Anchor, Preformed	B	2a	2	1	N	N
72030	Applicator, Rapid Wax, Dental	B	2a	1	2	N	N
72031	Applicator, Resin	A	1	2	1	N	N
72032	Articulators	D	3	1	1	N	N
72033	Attachment, Precision, All	A	1	2	1	N	N
72034	Band, Elastic, Orthodontic	B	2a	2	1	N	N
72035	Band, Material, Orthodontic	B	2a	2	1	N	N
72036	Band, Preformed, Orthodontic	B	2a	2	1	N	N
72037	Bar, Preformed	A	1	2	1	N	N
72038	Barrier, Animal Source, Intraoral	D	3	2	2	Y	N
72039	Barrier, Synthetic, Intraoral	D	3	2	2	Y	N
72040	Biologic Material, Dental	D	3	3	3	Y	N
72041	Blade-Form Endosseous Dental Implant	C	2b	3	3	Y	N
72042	Bone Grafting Material, Animal Source	C	2b	4	2	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72043	Bone Grafting Material, Dental, With Biologic Component	D	3	4	3	Y	N
72044	Bone Grafting Material, For Dental Bone Repair	C	2b	3	2	Y	N
72045	Bone Grafting Material, Human Source	C	2b	4	2	Y	N
72046	Bone Grafting Material, Synthetic	C	2b	3	2	Y	N
72047	Bracket, Ceramic, Orthodontic	B	2a	2	2	N	N
72048	Bracket, Metal, Orthodontic	B	2a	2	1	N	N
72049	Bracket, Metal, Orthodontic, Reprocessed	B	2a	2	1	N	N
72050	Bracket, Plastic, Orthodontic	B	2a	2	2	N	N
72051	Bracket, Plastic, Orthodontic, Reprocessed	B	2a	2	2	N	N
72052	Broach, Endodontic	B	2a	2	1	N	N
72053	Bur, Dental	B	2a	2	1	N	N
72054	Bur, Diamond Coated, Reprocessed	B	2a	2	1	N	N
72055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	A	1	1	1	N	N
72056	Capsule, Dental, Amalgam	B	2a	1	1	N	N
72057	Carboxymethylcellulose Sodium Or Polyvinyl Methylether Maleic Acid Calcium-Sodium	A	1	2	1	N	N
72058	Caries Detector, Laser Light, Transmission	D	3	2	2	N	N
72059	Carrier, Amalgam, Operative	A	1	1	1	N	N
72060	Carver, Dental Amalgam, Operative	A	1	1	1	N	N
72061	Carver, Wax, Dental	A	1	1	1	N	N
72062	Cement, Dental	B	2a	3	2	N	N
72063	Cement, Ear, Nose And Throat	D	3	3	2	Y	N
72064	Cephalometer	C	2b	1	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72066	Chair, Dental, With Operative Unit	B	2a	1	1	N	N
72067	Chair, Dental, Without Operative Unit	A	1	1	1	N	N
72068	Chisel, Bone, Surgical	B	2a	1	1	N	N
72069	Chisel, Osteotome, Surgical	B	2a	1	1	N	N
72070	Clamp, Rubber Dam	A	1	1	1	N	N
72071	Clamp, Wire, Orthodontic	B	2a	2	1	N	N
72072	Clasp, Preformed	A	1	2	1	N	N
72073	Clasp, Wire	A	1	2	1	N	N
72074	Cleaner, Denture, Mechanical	A	1	1	1	N	N
72075	Cleanser, Denture, Over The Counter	A	1	1	1	N	N
72076	Cleanser, Denture, Prescription	A	1	2	1	N	N
72077	Cleanser, Root Canal	D	3	3	U	N	N
72078	Coating, Denture Hydrophilic, Resin	A	1	2	2	N	N
72079	Coating, Filling Material, Resin	B	2a	3	2	N	N
72080	Collimator, X-Ray	C	3	2	1	N	N
72081	Condenser, Amalgam And Foil, Operative	A	1	1	1	N	N
72082	Cone, Radiographic, Lead-Lined	C	2b	2	1	N	N
72083	Controller, Foot, Handpiece And Cord	B	2a	2	1	N	N
72084	Cord, Retraction	A or D	1 or 3	3	U	N	N
72085	Cotton, Roll	A	1	1	1	N	N
72086	Crown And Bridge, Temporary, Resin	D	3	2	2	N	N
72087	Crown, Preformed	B	2a	3	1	N	N
72088	Cup, Prophylaxis	B	2a	1	1	N	N
72089	Curette, Endodontic	D	3	2	1	N	N
72090	Curette, Operative	D	3	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
872 DENTAL DEVICES							
72091	Curette, Periodontic	B	2a	1	1	N	N
72092	Curette, Surgical, Dental	B	2a	2	1	N	N
72093	Cushion, Denture, Over The Counter	A	1	2	2	N	N
72094	Cushion, Pad, Denture, Wax Impregnated Cotton, Over The Counter	A	1	2	1	N	N
72095	Cusp, Gold And Stainless Steel	B	2a	2	1	N	N
72096	Cusp, Preformed	B	2a	2	1	N	N
72097	Dam, Rubber	D	3	1	1	N	N
72098	Dental Amalgam	B	2a	3	2	N	N
72099	Dental Cement W/Out Zinc-Oxide Eugenol As An Ulcer Covering For Pain Relief	A	1	3	2	N	N
72100	Dental Fixture Mount Kit	A	1	1	1	N	N
72101	Dental Hygiene Kit	B	2a	1	1	N	N
72102	Dental Implant Surgical Tray (Kit)	C	2b	1	1	N	N
72103	Dental Lapping Tool Kit	B	3	1	1	N	N
72104	Dental Prophylaxis Kit	B	2a	1	2	N	N
72105	Denture Preformed (Partially Prefabricated Denture)	A	1	2	2	N	N
72106	Denture, Cosmetic Only	A	1	2	U	N	N
72107	Denture, Plastic, Teeth	A	1	2	2	N	N
72108	Dentures, Full	A	1	2	U	N	N
72109	Dentures, Partial	A	1	2	U	N	N
72110	Detector, Ultraviolet	A	1	2	2	N	N
72111	Device, Anti-Snoring	B	2a	1	2	N	N
72112	Device, Caries Detection	A	1	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72113	Device, Dental Sonography, For Diagnosis Of Tmj/Mpd Disorders	B	2a	2	2	N	N
72114	Device, Dental Sonography, For Monitoring Jaw Sounds	B	2a	2	1	N	N
72115	Device, Detection, Sulfide	B	2a	2	2	N	N
72116	Device, Electrical Dental Anesthesia	B	2a	2	U	N	N
72117	Device, Jaw Repositioning	B	2a	2	2	N	N
72118	Device, Jaw Tracking, For Diagnosis Of Tmj/Mpd Disorders	B	2a	2	2	N	N
72119	Device, Jaw Tracking, For Monitoring Jaw Positions	B	2a	2	1	N	N
72120	Diagnostic Light, Soft Tissue Detector	B	2a	2	2	N	N
72121	Disk, Abrasive	B	2a	1	1	N	N
72122	Dispenser, Mercury And/Or Alloy	A	1	1	1	N	N
72123	Drill, Bone, Powered	B	2a	2	2	N	N
72124	Drill, Dental, Intraoral	B	2a	2	1	N	N
72125	Driver, Band, Orthodontic	A	1	1	1	N	N
72126	Driver, Wire, And Bone Drill, Manual	B	2a	2	2	N	N
72127	Elevator, Surgical, Dental	B	2a	1	1	N	N
72128	Endodontic Kit	B	2a	2	2	N	N
72129	Eraser, Dental Stain	A	1	1	1	N	N
72130	Evacuator, Oral Cavity	B	2a	1	1	N	N
72131	Excavator, Dental, Operative	B	2a	1	1	N	N
72132	Expiratory Resistance Valve, Intranasal, For Obstructive Sleep Apnea	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72133	Explorer, Operative	A	1	1	1	N	N
72134	External Mandibular Fixator And/Or Distractor	C	2b	2	2	Y	N
72135	Facebow	A	1	2	1	N	N
72136	File, Bone, Surgical	B	2a	1	1	N	N
72137	File, Margin Finishing, Operative	A	1	1	1	N	N
72138	File, Periodontic	B	2a	1	1	N	N
72139	File, Pulp Canal, Endodontic	B	2a	2	1	N	N
72140	Floss, Dental	A	1	1	1	N	N
72141	Forceps, Articulation Paper	A	1	1	1	N	N
72142	Forceps, Dressing, Dental	D	3	1	1	N	N
72143	Forceps, Rongeur, Surgical	B	2a	1	1	N	N
72144	Forceps, Rubber Dam Clamp	A	1	1	1	N	N
72145	Forceps, Tooth Extractor, Surgical	B	2a	1	1	N	N
72146	Frame, Rubber Dam	A	1	1	1	N	N
72147	Gauge, Depth, Instrument, Dental	B	2a	1	1	N	N
72148	Gel, Electrode, For Pulp Tester	B	2a	2	1	N	N
72149	General Purpose Dental Tray (Kit)	A	1	1	1	N	N
72150	Gingival Retraction Kit	A or D	1 or 3	3	U	N	N
72151	Glenoid Fossa Prosthesis	C	2b	3	3	N	N
72152	Guard, Disk	A	1	1	1	N	N
72153	Gutta-Percha	B	2a	3	1	N	N
72154	Handle, Instrument, Dental	A	1	1	1	N	N
72155	Handpiece, Air-Powered, Dental	B	2a	2	1	N	N
72156	Handpiece, Air-Powered, Root Canal Irrigation	B	2a	2	1	N	N
72157	Handpiece, Belt And/Or Gear Driven, Dental	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72158	Handpiece, Contra- And Right-Angle Attachment, Dental	B	2a	2	1	N	N
72159	Handpiece, Direct Drive, Ac-Powered	B	2a	2	1	N	N
72160	Handpiece, Rotary Bone Cutting	B	2a	2	2	N	N
72161	Handpiece, Water-Powered	B	2a	2	1	N	N
72162	Headgear, Extraoral, Orthodontic	A	1	2	2	N	N
72163	Heat Source For Bleaching Teeth	B	2a	2	1	N	N
72164	Hemostat, Surgical	A	1	1	1	N	N
72165	Hoe, Periodontic	B	2a	1	1	N	N
72166	Holder, Film, X-Ray	B	2a	1	1	N	N
72167	Implant, Endosseous, Orthodontic	C	2b	3	2	Y	N
72168	Implant, Endosseous, Root-Form	C	2b	3	2	Y	N
72169	Implant, Subperiosteal	C	2b	3	2	Y	N
72170	Implant, Transmandibular	C	3	3	2	Y	N
72171	Injector, Jet, Gas-Powered	B	3	2	2	N	N
72172	Injector, Jet, Mechanical-Powered	B	3	2	2	N	N
72173	Ink, Arch Tracing	A	3	2	1	N	N
72174	Instrument, Contouring, Matrix, Operative	A	3	1	1	N	N
72175	Instrument, Cutting, Operative	B	3	1	1	N	N
72176	Instrument, Diamond, Dental	B	3	2	1	N	N
72177	Instrument, Diamond, Dental, Reprocessed	B	3	2	1	N	N
72178	Instrument, Filling, Plastic, Dental	A	3	1	1	N	N
72179	Instrument, Hand, Calculus Removal	B	3	1	1	N	N
72180	Instrument, Ligature Tucking, Orthodontic	A	1	1	1	N	N
72181	Instruments, Dental Hand	A	3	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72182	Interarticular Disc Prosthesis (Interpositional Implant)	C	3	3	3	Y	N
72183	Intraoral Pressure Gradient Device	B	3	2	2	N	N
72184	Joint, Temporomandibular, Implant	C	3	3	3	Y	N
72185	Kit, Test, In Vitro Periodontal	B	3	2	3	N	N
72186	Knife, Margin Finishing, Operative	A	3	2	1	N	N
72187	Knife, Periodontic	B	3	2	1	N	N
72188	Laser, Dental	D	3	3	U	N	N
72189	Laser, Fluorescence Caries Detection	A	3	2	2	N	N
72190	Light, Fiber Optic, Dental	A	3	1	1	N	N
72191	Light, Operating, Dental	A	3	1	1	N	N
72192	Light, Surgical Headlight	A	3	1	1	N	N
72193	Liner, Cavity, Calcium Hydroxide	D	3	3	2	N	N
72194	Locator, Root Apex	B	3	2	U	N	N
72195	Lock, Wire, And Ligature, Intraoral	A	1	3	2	Y	N
72196	Maintainer, Space Preformed, Orthodontic	B	2a	2	1	N	N
72197	Mandibular Condyle Prosthesis	C	2b	3	3	N	N
72198	Marker, Periodontic	B	2a	1	1	N	N
72199	Material, Dressing, Surgical, Polylactic Acid	C	3	3	3	N	N
72200	Material, Impression	A	1	1	2	N	N
72201	Material, Impression Tray, Resin	A	1	1	1	N	N
72202	Material, Tooth Shade, Resin	B	2a	3	2	N	N
72203	Materials, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Alveolar Ridge Augmentation	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
872 DENTAL DEVICES							
72204	Measurer, Gingival Fluid	A	1	1	1	N	N
72205	Mercury	B	2a	3	2	N	N
72206	Mirror, Mouth	A	1	1	1	N	N
72207	Mouthguard, Migraine/Tension Headache	B	2a	2	U	N	N
72208	Mouthguard, Over-The-Counter	A	1	1	U	N	N
72209	Mouthguard, Prescription	A	1	2	U	N	N
72210	Mouthpiece, Saliva Ejector	B	2a	1	1	N	N
72211	Needle, Dental	B	2a	2	1	N	N
72212	Needle, Dental, Reprocessed	B	2a	2	1	N	N
72213	Oral Irrigation Kit	B	2a	2	1	N	N
72214	Oral Wound Dressing	B	2a	2	U	N	N
72215	Oral Wound Dressing W/Drug And/Or Biologic	B	2a	2	U	N	N
72216	Orthodontic Vibratory Accessory	B	2a	2	2	N	N
72217	Over The Counter Denture Repair Kit	A	1	2	2	N	N
72218	Pad, Denture, Over The Counter	A	1	2	2	N	N
72219	Pantograph	A	1	1	1	N	N
72220	Paper, Articulation	A	1	1	1	N	N
72221	Parallelometer	A	1	1	1	N	N
72222	Patient Personal Hygiene Kit	A	1	1	1	N	N
72223	Pick, Massaging	A	1	1	1	N	N
72224	Pillow,Cervical(For Mild Sleep Apnea)	A	1	1	2	N	N
72225	Pin, Retentive And Splinting, And Accessory Instruments	B	2a	3	1	N	N
72226	Plaque Disclosing Kit	A	1	1	2	N	N
72227	Plate, Base, Shellac	A	1	1	1	N	N
72228	Plate, Bone	C	2b	3	2	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72229	Plier, Orthodontic	A	1	1	1	N	N
72230	Pliers, Operative	A	1	1	1	N	N
72231	Plugger, Root Canal, Endodontic	B	2a	1	1	N	N
72232	Point, Abrasive	B	2a	1	1	N	N
72233	Point, Paper, Endodontic	A	1	2	1	N	N
72234	Point, Silver, Endodontic	B	2a	3	1	N	N
72235	Polyvinyl Methylether Maleic Anhydride &/Or Acid Copolymer & Carboxymethylce	A	1	3	3	N	N
72236	Positioner, Tooth, Preformed	B	2a	2	1	N	N
72237	Post, Root Canal	B	2a	3	1	N	N
72238	Powder, Porcelain	B	2a	3	2	N	N
72239	Prelude Tongue Suspension System	B	2a	2	2	Y	N
72239	Prelude Tongue Suspension System	B	2a	2	2	Y	N
72240	Preparer, Root Canal Endodontic	B	2a	1	1	N	N
72241	Probe, Periodontic	A	1	1	1	N	N
72242	Prosthesis, Condyle, Mandibular, Temporary	C	2b	3	3	Y	N
72243	Prosthesis, Orthodontic	B	2a	3	U	N	N
72244	Protector, Silicate	B	2a	1	1	N	N
72245	Punch, Biopsy, Surgical	B	2a	2	1	N	N
72246	Pusher, Band, Orthodontic	A	1	1	1	N	N
72247	Reamer, Pulp Canal, Endodontic	B	2a	2	1	N	N
72248	Reliner, Denture, Over The Counter	A	1	2	2	N	N
72249	Remover, Crown	A	1	1	1	N	N
72250	Resin, Denture, Relining, Repairing, Rebasing	A	1	2	2	N	N
72251	Resin, Root Canal Filling	B	2a	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72252	Resin, Root Canal Filling Containing Chloroform	B	2a	3	3	N	N
72253	Restoration, Base Metal	B	2a	3	U	N	N
72254	Restoration, Noble Metal	D	2a	3	U	N	N
72255	Restoration, Porcelain	D	2a	3	U	N	N
72256	Restoration, Porcelain-Fused-To-Metal	D	2a	3	U	N	N
72257	Restoration, Resin	D	2a	3	U	N	N
72258	Restoration, Resin, Crown And Bridge	D	2a	3	U	N	N
72259	Restorative Instrument And Component Tray (Kit)	D	2a	1	2	N	N
72260	Retainer, Matrix	D	1	1	1	N	N
72261	Retainer, Screw Expansion, Orthodontic	D	2a	2	1	N	N
72262	Retractor, All Types	A	1	1	1	N	N
72263	Ring, Teething, Fluid-Filled	A	1	2	2	N	N
72264	Ring, Teething, Non-Fluid Filled	A	1	1	1	N	N
72265	Rinse, Oral, Antibacterial (By Physical Means)	A	1	2	2	N	N
72266	Saliva, Artificial	D	3	3	U	N	N
72267	Saw, Bone, Ac-Powered	B	2a	2	2	N	N
72268	Scaler, Periodontic	B	2a	1	1	N	N
72269	Scaler, Rotary	B	2a	2	2	N	N
72270	Scaler, Ultrasonic	B	2a	2	2	N	N
72271	Scanner, Color	A	1	2	2	N	N
72272	Scissors, Collar And Crown	A	1	1	1	N	N
72273	Scissors, Surgical Tissue, Dental	B	2a	1	1	N	N
72274	Scraper, Tongue	A	1	1	1	N	N
72275	Screw, Fixation, Intraosseous	C	2b	3	2	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72276	Sealant, Pit And Fissure, And Conditioner	B	2a	3	2	N	N
72277	Setter, Band, Orthodontic	A	1	1	1	N	N
72278	Solution, Cement Dissolving	A	1	3	2	N	N
72279	Solution, Removal, Carries	B	2a	2	3	N	N
72280	Splint, Endodontic Stabilizing	C	2b	3	2	N	N
72281	Spreader, Pulp Canal Filling Material, Endodontic	B	2a	2	1	N	N
72282	Spring, Orthodontic	B	2a	2	1	N	N
72283	Sterilizer, Boiling Water	B	2a	2	1	N	N
72284	Sterilizer, Endodontic Dry Heat	B	2a	2	3	N	N
72285	Sterilizer, Glass Bead	B	2a	2	3	N	N
72286	Stimulator, Salivary System	B	2a	2	3	N	N
72287	Strip, Polishing Agent	B	2a	1	1	N	N
72288	Suture, Dental	C	2b	3	3	Y	N
72289	Syringe, Cartridge	A	1	2	2	N	N
72290	Syringe, Irrigating (Dental)	B	2a	2	1	N	N
72291	Syringe, Periodontic, Endodontic, Irrigating	B	2a	2	1	N	N
72292	Syringe, Restorative And Impression Material	B	2a	2	1	N	N
72293	System, Optical Impression, Computer Assisted Design And Manufacturing (Cad/Cam) Of Dental Restorations	A	1	2	2	N	N
72294	System,Dental,Hydrokinetic,Carries Removal & Cavity Preparation	B	2a	3	2	N	N
72295	System,X-Ray,Extraoral Source,Digital	B	2a	2	2	N	N
72296	Teeth, Artificial, Backing And Facing	B	2a	2	1	N	N
72297	Teeth, Artificial, Posterior With Metal Insert	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
872 DENTAL DEVICES							
72298	Teeth, Porcelain	B	2a	2	2	N	N
72299	Teeth, Preformed Gold Denture	A	1	2	1	N	N
72300	Tester, Pulp	B	2a	2	2	N	N
72301	Tip, Rubber, Oral Hygiene	A	1	1	1	N	N
72302	Toothbrush, Ionic, Battery-Powered	B	2a	2	1	N	N
72303	Toothbrush, Manual	A	1	1	1	N	N
72304	Toothbrush, Powered	B	2a	2	1	N	N
72305	Tray, Fluoride, Disposable	A	1	1	1	N	N
72306	Tray, Impression, Preformed	A	1	1	1	N	N
72307	Tube Impression And Matrix	A	1	1	1	N	N
72308	Tube, Orthodontic	B	2a	2	1	N	N
72309	Unit, Electrosurgical, And Accessories, Dental	C	2b	3	2	N	N
72310	Unit, Operative Dental	B	2a	2	1	N	N
72311	Unit, Operative Dental, Accessories	B	2a	1	1	N	N
72312	Unit, Oral Irrigation	B	2a	2	1	N	N
72313	Unit, Suction Operatory	B	2a	2	1	N	N
72314	Unit, Syringe, Air And/Or Water	B	2a	2	1	N	N
72315	Unit, Ultraviolet Sanitation/Sterilization (For Toothbrushes), Non-Sterile	B	2a	2	1	N	N
72316	Unit, Ultraviolet Sanitation/Sterilization (For Toothbrushes), Sterile	B	2a	2	1	N	N
72317	Unit, X-Ray, Extraoral With Timer	C	2b	3	2	N	N
72318	Unit, X-Ray, Intraoral	C	2b	2	2	N	N
72319	Varnish, Cavity	B	2a	3	2	N	N
72320	Warmer, Anesthetic Tube	A	1	1	1	N	N
72321	Wax, Dental, Intraoral	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
872 DENTAL DEVICES							
72322	Wheel, Polishing Agent	B	2a	1	1	N	N
72323	Wire, Fixation, Intraosseous	C	2b	3	2	Y	N
72324	Wire, Orthodontic	B	2a	2	1	N	N
72325	Zinc Oxide Eugenol	C	2b	3	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
874 EAR, NOSE, AND THROAT DEVICES							
74001	Adaptor, Short Increment Sensitivity Index (Sisi)	B	2a	2	1	N	N
74002	Adenotome	A	1	1	1	N	N
74003	Aid, Visual, For Nausea	B	2a	2	N	N	N
74004	Aids, Speech Training For The Hearing Impaired (Ac-Powered And Patient-Contact)	B	2a	2	U	N	N
74005	Aids, Speech Training For The Hearing Impaired (Battery-Operated Or Non-Patient)	B	2a	2	U	N	N
74006	Apparatus, Vestibular Analysis	B	2a	2	U	N	N
74007	Apparatus, Visual Reinforcement Audiometric	B	2a	2	U	N	N
74008	Applicator, Ent	A	1	1	1	N	N
74009	Applicator, Ent Drug	A	1	1	1	N	N
74010	Audiometer	B	2a	2	2	N	N
74011	Balloon, Epistaxis	A	1	1	1	N	N
74011	Balloon, Epistaxis	A	1	1	1	N	N
74012	Bistoury, Tracheal	A	1	1	1	N	N
74013	Block, Cutting, Ent, Non-Sterile	A	1	1	1	N	N
74014	Block, Cutting, Ent, Sterile	A	1	1	1	N	N
74015	Blower, Powder, Ent	A	1	1	1	N	N
74016	Bone Particle Collector	A	1	1	1	N	N
74017	Bougie, Esophageal, Ent	B	2a	2	1	N	N
74018	Bougie, Eustachian	B	2a	2	1	N	N
74019	Bronchoscope (Flexible Or Rigid)	B	2a	2	2	N	N
74020	Bronchoscope Accessory	B	2a	2	2	N	N
74021	Brush, Biopsy, Bronchoscope (Non-Rigid)	B	2a	2	2	N	N
74022	Bur, Ear, Nose And Throat	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
874 EAR, NOSE, AND THROAT DEVICES							
74023	Bur, Ent, Diamond Coated, Single Use, Reprocessed	B	2a	2	1	N	N
74024	Button, Nasal Septal	B	2a	2	U	Y	N
74025	Calibrator, Hearing Aid / Earphone And Analysis Systems	B	2a	2	2	N	N
74026	Catheter, Nasopharyngeal	A	1	1	1	N	N
74027	Chamber, Acoustic (For Audiometric Testing)	A	1	1	1	N	N
74028	Chisel, Middle-Ear	A	1	1	1	N	N
74029	Clamp, Ossicle Holding	B	2a	2	1	N	N
74030	Claw, Foreign Body, Bronchoscope (Non-Rigid)	A	1	1	2	N	N
74031	Collagen, Injectable For Vocal Cord Augmentation	D	3	3	U		N
74032	Crimper, Wire, Ent, Non-Sterile	A	1	1	1	N	N
74033	Crimper, Wire, Ent, Sterile	A	1	1	1	N	N
74034	Curette, Adenoid	B	2a	2	1	N	N
74035	Curette, Biopsy, Bronchoscope (Rigid)	B	2a	2	2	N	N
74036	Curette, Ear	B	2a	2	1	N	N
74037	Curette, Ethmoid	B	2a	2	1	N	N
74038	Curette, Nasal	B	2a	2	1	N	N
74039	Curette, Salpingeal	B	2a	2	1	N	N
74040	Curette, Biopsy, Bronchoscope (Non-Rigid)	B	2a	2	2	N	N
74041	Cushion, Earphone (For Audiometric Testing)	A	1	1	1	N	N
74042	Depressor, Metal Tongue, Surgical	A	1	1	1	N	N
74043	Device, Antichoke, Suction	C	2b	3	3	N	N
74044	Device, Antichoke, Tongs	B	2a	2	3	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74045	Device, Anti-Stammering	B	2a	2	1	N	N
74046	Device, Assistive Listening	B	2a	2	U	N	N
74047	Device, Inflation, Middle Ear	C	2b	3	U	N	N
74048	Device, Voice Amplification	B	2a	2	2	N	N
74049	Die, Wire Bending, Ent, Non-Sterile	A	1	1	1	N	N
74050	Die, Wire Bending, Ent, Sterile	A	1	1	1	N	N
74051	Dilator, Esophageal, Ent	B	2a	2	1	N	N
74052	Dilator, Nasal	A	1	1	1	N	N
74053	Dilator, Tracheal	A	1	1	1	N	N
74054	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	1	N	N
74055	Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece	B	2a	2	2	N	N
74056	Dropper, Ent	A	1	1	1	N	N
74057	Drug-Eluting Sinus Stent	D	3	3	3	Y	N
74058	Ear Wick	A	1	1	1	N	N
74059	Ear, Nose, And Throat Surgical Tray (Kit)	B	2a	2	1	N	N
74060	Elastomer, Silicone Block	C	2b	3	2	Y	N
74061	Electroglottograph	B	2a	2	2	N	N
74062	Electronic Media, Hyperacusis	D	3	2	U	N	N
74063	Elevator, Ent	A	1	1	1	N	N
74064	Esophagoscope (Flexible Or Rigid)	B	2a	2	2	N	N
74065	Excavator, Ear	A	1	1	1	N	N
74066	Face Plate Hearing Aid	B	2a	2	1	N	N
74067	Forceps, Biopsy, Bronchoscope (Non-Rigid)	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
874 EAR, NOSE, AND THROAT DEVICES							
74068	Forceps, Biopsy, Bronchoscope (Non-Rigid), Reprocessed	B	2a	2	2	N	N
74069	Forceps, Biopsy, Bronchoscope (Rigid)	B	2a	2	2	N	N
74070	Forceps, Ent	A	1	1	1	N	N
74071	Forceps, Wire Closure, Ent, Non-Sterile	A	1	1	1	N	N
74072	Forceps, Wire Closure, Ent, Sterile	A	1	1	1	N	N
74073	Gag, Mouth	A	1	1	1	N	N
74074	Gauge, Mastoid	A	1	1	1	N	N
74075	Gauge, Measuring	A	1	1	1	N	N
74076	Generator, Electronic Noise (For Audiometric Testing)	B	2a	2	2	N	N
74077	Gouge, Nasal, Ent	A	1	1	1	N	N
74078	Guillotine, Tonsil	A	3	1	1	N	N
74079	Gustometer, Non-Sterile	B	2a	2	1	N	N
74080	Gustometer, Sterile	B	2a	2	1	N	N
74081	Hearing Aid, Air Conduction	B	2a	2	1	N	N
74082	Hearing Aid, Air Conduction With Wireless Technology	B	2a	2	2	N	N
74083	Hearing Aid, Air Conduction, Transcutaneous System	C	2b	3	2	Y	N
74084	Hearing Aid, Bone Conduction	D	3	3	2	N	N
74085	Hearing Aid, Bone Conduction, Implanted	C	2b	3	2	Y	N
74086	Hearing Aid, Group And Auditory Trainer	B	2a	2	2	N	N
74087	Hearing Aid, Master	D	3	2	2	N	N
74088	Hearing Aid, Tactile	D	3	2	U	N	N
74089	Hook, Microsurgical Ear	A	1	1	1	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74090	Hook, Tonsil Suturing	A	1	1	1	N	N
74091	Hook, Tracheal	A	1	1	1	N	N
74092	Implant, Cochlear	C	2b	3	3	Y	N
74093	Implant, Hearing, Active, Middle Ear, Partially Implanted	C	2b	3	3	Y	N
74094	Implant, Hearing, Active, Middle Ear, Totally Implanted	C	2b	3	3	Y	N
74095	Inhaler, Nasal	D	3	1	1	N	N
74096	Insertor, Myringotomy Tube	A	1	1	1	N	N
74097	Insertor, Sacculotomy Tack	A	1	1	1	N	N
74098	Instrument, Ent Manual Surgical	A	1	1	1	N	N
74099	Instrument, Prosthesis Modification For Ossicular Replacement Surgery, Non-Sterile	A	1	1	1	N	N
74100	Instrument, Prosthesis Modification For Ossicular Replacement Surgery, Sterile	A	1	1	1	N	N
74101	Irrigator, Powered Nasal	A	3	1	1	N	N
74102	Irrigator, Sinus	A	1	1	1	N	N
74103	Jig, Piston Cutting, Ent, Non-Sterile	B	2a	2	1	N	N
74104	Jig, Piston Cutting, Ent, Sterile	B	2a	2	1	N	N
74105	Kit, Earmold, Impression	A	1	1	U	N	N
74106	Kit, Test, Olfactory	B	2a	2	2	N	N
74107	Knife, Ear	B	2a	2	1	N	N
74108	Knife, Ent	B	2a	2	1	N	N
74109	Knife, Laryngeal	B	2a	2	1	N	N
74110	Knife, Myringotomy	B	2a	2	1	N	N
74111	Knife, Nasal	B	2a	2	1	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74112	Knife, Tonsil	B	2a	2	1	N	N
74113	Laryngoscope, Nasopharyngoscope	B	2a	2	2	N	N
74114	Laryngostroboscope	B	2a	2	1	N	N
74115	Larynx, Artificial (Battery-Powered)	B	2a	2	1	N	N
74116	Laser, Ent Microsurgical Carbon-Dioxide	C	2b	3	2	N	N
74117	Laser, Microsurgical Argon, For Use In Otology	C	2b	3	2	N	N
74118	Laser, Microsurgical Argon, For Uses Other Than Otology, Including Laryngology & General Use In Otolaryngology	C	2b	3	2	N	N
74119	Laser, Neodymium:Yag, Pulmonary Surgery	C	2b	3	2	N	N
74120	Loop, Wire	A	1	1	1	N	N
74121	Masker, Tinnitus	B	2a	2	2	N	N
74122	Mediastinoscope, Surgical	B	2a	2	2	N	N
74123	Microdebrider, Ent, High Speed, Single Use, Reprocessed	B	2a	2	1	N	N
74124	Microrule, Ent	A	1	1	1	N	N
74125	Mirror, Ent	A	1	1	1	N	N
74126	Mobilizer, Ent	A	1	1	1	N	N
74127	Mold, Middle-Ear	C	2b	3	2	Y	N
74128	Myringotomy Procedure Kit	B	2a	2	2	N	N
74130	Nasograph	B	2a	2	U	N	N
74131	Nasopharyngoscope (Flexible Or Rigid)	B	2a	2	2	N	N
74132	Needle, Tonsil Suturing	B	2a	2	1	N	N
74133	Nipper, Malleus	A	1	1	1	N	N
74134	Otoscope	A	1	1	1	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74135	Paste, Injectable For Vocal Cord Augmentation	C	2b	3	3	N	N
74136	Perforator, Antrum	A	1	1	1	N	N
74137	Perforator, Ear-Lobe	A	1	1	1	N	N
74138	Pick, Microsurgical Ear	A	1	1	1	N	N
74139	Pierced Ear/Entry Cleaning Tray	A	1	1	U	N	N
74140	Polymer, Ear, Nose And Throat, Synthetic, Absorbable	C	2b	3	2	N	N
74141	Polymer, Ent Natural-Collagen Material	D	3	3	U	N	N
74142	Polymer, Ent Synthetic, Porous Polyethylene	C	2b	3	2	Y	N
74143	Polymer, Ent Synthetic-Pipe, Silicon Elastomer, Polyethylene, Polyurethane	C	2b	3	2	Y	N
74144	Polymer, Ent Synthetic-Polyamide (Mesh Or Foil Material)	C	2b	3	2	Y	N
74145	Polymer, Natural-Absorbable Gelatin Material	C	2b	3	3	N	N
74146	Porous Polyethylene Ossicular Replacement	C	2b	3	2	Y	N
74147	Press, Vein	A	1	1	1	N	N
74148	Probe, Ent	A	1	1	1	N	N
74149	Prosthesis, Facial, Mandibular Implant	C	2b	3	2	Y	N
74150	Prosthesis, Laryngeal (Taub)	C	2b	3	2	N	N
74151	Prosthesis, Larynx (Stents And Keels)	C	2b	3	U	N	N
74154	Protector, Hearing (Circumaural)	A	1	1	U	N	N
74155	Protector, Hearing (Insert)	A	1	1	U	N	N
74156	Pump, Nebulizer, Electrically Powered	B	2a	2	1	N	N
74157	Pump, Nebulizer, Manual	B	2a	3	1	N	N
74158	Punch, Adenoid	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
874 EAR, NOSE, AND THROAT DEVICES							
74159	Punch, Antrum	A	1	1	1	N	N
74160	Punch, Attic	A	1	1	1	N	N
74161	Punch, Ent	A	1	1	1	N	N
74162	Punch, Ethmoid	A	1	1	1	N	N
74163	Punch, Gelfoam, Sterile	A	1	1	1	N	N
74164	Punch, Nasal	A	1	1	1	N	N
74165	Punch, Tonsil	A	1	1	1	N	N
74166	Punch, Gelfoam, Non-Sterile	A	1	1	1	N	N
74167	Rasp, Ear	A	1	1	1	N	N
74168	Rasp, Frontal-Sinus	A	1	1	1	N	N
74169	Rasp, Nasal	A	1	1	1	N	N
74170	Replacement, Ossicular (Stapes) Using Absorbable Gelatin Material	C	2b	3	2	Y	N
74172	Replacement, Total Ossicular, Prosthesis, Porous, Polyethylene	C	3	3	2	Y	N
74173	Retractor, Ent	A	3	1	1	N	N
74174	Rod, Measuring Ear	A	3	1	1	N	N
74175	Rongeur, Mastoid	A	3	1	1	N	N
74176	Rongeur, Nasal	A	3	1	1	N	N
74177	Saw, Laryngeal	A	3	1	1	N	N
74178	Saw, Nasal	A	3	1	1	N	N
74179	Saw, Surgical, Ent (Electric Or Pneumatic)	B	3	2	1	N	N
74180	Scissors, Ear	A	3	1	1	N	N
74181	Scissors, Nasal	A	3	1	1	N	N
74182	Scissors, Wire Cutting, Ent, Non-Sterile	A	1	1	1	N	N
74183	Scissors, Wire Cutting, Ent, Sterile	A	3	1	1	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74184	Screw, Oral	A	3	1	1	N	N
74185	Screw, Tonsil	A	3	1	1	N	N
74186	Searcher, Mastoid	A	3	1	1	N	N
74187	Set, Audiometer Calibration	B	3	2	1	N	N
74188	Set, Filliform, Eustachian	A	3	1	1	N	N
74189	Set, Laryngeal Injection	B	3	2	1	N	N
74190	Snare, Ear	D	3	1	1	N	N
74191	Snare, Nasal	A	3	1	1	N	N
74192	Snare, Tonsil	A	3	1	1	N	N
74193	Source, Carrier, Fiberoptic Light	A	3	1	1	N	N
74194	Splint, Intranasal Septal	A	3	1	1	N	N
74195	Splint, Nasal	A	3	1	1	N	N
74196	Spoon, Ear	A	3	1	1	N	N
74197	Stimulator, Caloric-Air	B	2a	2	1	N	N
74198	Stimulator, Caloric-Water	B	2a	2	1	N	N
74199	Stimulator, Nerve	B	2a	2	2	N	N
74200	Support, Head, Surgical, Ent	A	1	1	U	N	N
74201	Syringe, Ent	B	3	2	1	N	N
74203	Tack, Sacculotomy (Cody Tack)	C	2b	3	2	Y	N
74204	Telescope, Laryngeal-Bronchial	B	2a	2	2	N	N
74205	Tester, Auditory Impedance	B	2a	2	2	N	N
74206	Tonsillectome	A	1	1	1	N	N
74207	Tracheotome	A	1	1	1	N	N
74208	Transilluminator, Fiber Optic	A	1	1	U	N	N
74209	Tray, Surgical, Ent	B	2a	2	1	N	N

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874 EAR, NOSE, AND THROAT DEVICES							
74210	Trephine, Sinus	A	1	1	1	N	N
74211	Trocar, Ent	B	2a	2	1	N	N
74212	Trocar, Laryngeal	B	2a	2	1	N	N
74213	Trocar, Sinus	B	2a	2	1	N	N
74214	Trocar, Tracheal	B	2a	2	1	N	N
74215	Trocar, Tracheal, Laryngeal, Sinus, Reprocessed	B	2a	2	1	N	N
74216	Tube, Aspirating, Bronchoscope, Rigid	B	2a	2	2	N	N
74217	Tube, Ear Suction	A	1	1	1	N	N
74218	Tube, Laryngectomy	B	2a	2	1	N	N
74220	Tube, Shunt, Endolymphatic With Valve	C	2b	3	2	Y	N
74221	Tube, Tonsil Suction	B	2a	2	1	N	N
74224	Tube, Tympanostomy With Semi-Permeable Membrane	C	2b	3	2	Y	N
74225	Tube, Tympanostomy, Porous Polyethylene	C	2b	3	2	Y	N
74226	Tubing, Instrumentation, Bronchoscope (Brush Sheath A/O Aspirating)	B	2a	2	2	N	N
74227	Tympanometer	B	2a	2	2	N	N
74228	Ultrasound, Sinus	B	2a	2	U	N	N
74230	Vise, Ossicular Finger, Non-Sterile	A	1	1	1	N	N
74231	Vise, Ossicular Finger, Sterile	A	1	1	1	N	N
74232	Tube, Toynbee Diagnostic	A	1	1	1	N	N
74233	Replacement, Ossicular Prosthesis, Total	C	2b	3	2	Y	N
74234	Prosthesis, Partial Ossicular Replacement	C	2b	3	2	Y	N
74235	Tube, Tympanostomy	C	2b	4	2	Y	N
74236	Unit, Examining/Treatment, Ent	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76001	Accessories, A-V Shunt	B	2a	2	2	Y	N
76002	Accessories, Blood Circuit, Hemodialysis	B	2a	2	2	N	Y
76003	Accessories, Catheter, G-U	B	2a	2	2	N	N
76004	Accessories, Cleaning Brushes, For Endoscope	B	2a	2	1	N	N
76005	Accessories, Cleaning, For Endoscope	B	2a	2	2	N	N
76006	Accessories, Germicide, Cleaning, For Endoscopes	B	2a	2	2	N	N
76007	Accessories, Photographic, For Endoscope (Exclude Light Sources)	A	1	1	1	N	N
76008	Adapter, A-V Shunt Or Fistula	B	2a	2	2	Y	N
76009	Adaptor To The Cord, For Transurethral Surgical Instrument	B	2a	2	2	N	N
76010	Adaptor, Bulbs, Miscellaneous, For Endoscope	B	2a	2	1	N	N
76011	Adaptor, Fistula	B	2a	2	2	N	N
76012	Adaptor, Shunt	B	2a	2	2	Y	N
76013	Adaptor, Ureteral Catheter	B	2a	2	1	N	N
76014	Adaptor, Y	B	2a	2	2	N	N
76015	Agent, Bulking, Injectable For Gastro-Urology Use	C	2b	3	3	N	N
76016	Alarm, Conditioned Response Enuresis	B	2a	2	2	N	N
76017	Alarm, Pillow Pressure	C	2b	3	2	N	Y
76018	Analyzer, Diagnostic, Fiber Optic (Colon)	C	2b	3	3	N	N
76019	Angioscope	B	2a	2	2	N	N
76020	Anoscope And Accessories	B	2a	2	2	N	N
76021	Anti Fog Solution And Accessories, Endoscopy	B	2a	2	2	N	N
76022	Apparatus, Hemoperfusion, Sorbent	C	2b	3	3	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76023	Apparatus, Pneumoperitoneum, Automatic	B	2a	2	2	N	N
76024	Appliance, Colostomy, Disposable	A	1	1	1	N	N
76025	Applicator For Rectal Suppository	A	1	1	1	N	N
76026	Attachment, Binocular, For Endoscope	A	1	1	1	N	N
76027	Attachment, Eyepiece, For Insertion Of Prescription Lens	A	1	1	1	N	N
76028	Attachment, Teaching, For Endoscope	A	1	1	1	N	N
76029	Autonomous Extracorporeal Blood Leak Detector/Alarm	C	2b	3	2	N	N
76030	Bag, Bile Collecting	B	2a	2	2	N	N
76031	Bag, Drainage, With Adhesive, Ostomy	A	1	1	1	N	N
76032	Bag, Hemostatic	D	3	2	2	N	N
76033	Bag, Stomal	A	1	1	1	N	N
76034	Bag, Urinary, Ileostomy	A	1	1	1	N	N
76035	Bag, Urine Collecting, Ureterostomy	A	1	1	1	N	N
76036	Endoscope, Accessories, Narrow Band Spectrum	B	2a	2	2	N	N
76037	Bag, Urine Collection, Leg, For External Use, Non-Sterile	A	1	1	1	N	N
76038	Bag, Urine Collection, Leg, For External Use, Sterile	A	1	1	1	N	N
76039	Bag, Urine Collection, Newborn	B	2a	2	2	N	N
76040	Balloon, Liver Tamponade	C	2b	3	2	N	N
76041	Biopsy Needle Kit	B	2a	2	2	N	N
76042	Bladder System	C	2b	3	U	Y	N
76043	Bougie, Esophageal, And Gastrointestinal, Gastro-Urology	B	2a	2	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76044	Bougie, Urological	B	2a	2	1	N	N
76045	Box, Battery, Pocket	A	1	1	1	N	N
76046	Box, Battery, Rechargeable	A	1	1	1	N	N
76047	Bulb, Inflation, For Endoscope	B	2a	2	1	N	N
76048	Canister, Coil	B	2a	2	2	N	Y
76049	Cannula And Trocar, Suprapubic, Non-Disposable	B	2a	2	1	N	N
76050	Cannula, A-V Shunt	C	2b	3	3	Y	N
76051	Carrier, Sponge, Endoscopic	A	1	1	2	N	N
76052	Catheter (Gastric, Colonic, Etc.), Irrigation And Aspiration	B	2a	2	2	N	N
76053	Catheter And Tube, Suprapubic	B	2a	2	2	Y	N
76054	Catheter Care Tray (Kit)	B	2a	2	2	N	N
76055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	2	Y	Y
76056	Catheter, Biliary, Reprocessed	B	2a	2	2	N	N
76057	Catheter, Biliary, Surgical	B	2a	2	2	N	N
76058	Catheter, Coude	D	3	2	2	N	N
76059	Catheter, Double Lumen Female Urethrographic	B	2a	2	2	N	N
76060	Catheter, Femoral	B	2a	2	2	Y	Y
76061	Catheter, Hemodialysis, Implanted	C	2b	3	3	Y	Y
76062	Catheter, Hemodialysis, Implanted, Coated	C	2b	3	3	Y	Y
76063	Catheter, Hemodialysis, Non-Implanted	D	3	2	2	N	Y
76064	Catheter, Hemodialysis, Non-Implanted, Ultrafiltration, For Peripheral Use	B	2a	2	2	N	Y
76065	Catheter, Hemodialysis, Triple Lumen, Implanted	C	2b	3	3	Y	Y

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76066	Catheter, Hemodialysis, Triple Lumen, Non-Implanted	C	2b	3	2	N	Y
76067	Catheter, Malecot	B	2a	2	2	N	N
76068	Catheter, Nephrostomy	B	2a	2	U	N	N
76069	Catheter, Peritoneal Dialysis, Single Use	B	2a	2	2	N	Y
76070	Catheter, Peritoneal, Long-Term Indwelling	C	2b	3	2	Y	N
76071	Catheter, Rectal	B	2a	2	2	N	N
76072	Catheter, Rectal For Continent Ileostomy	B	2a	2	1	N	N
76073	Catheter, Retention Type	B	2a	2	2	N	N
76074	Catheter, Retention Type, Balloon	B	2a	2	2	N	N
76075	Catheter, Retention, Barium Enema With Bag	B	2a	2	2	N	N
76076	Catheter, Straight	B	2a	2	2	N	N
76077	Catheter, Subclavian	B	2a	2	3	Y	N
76078	Catheter, Suction, Trachbronchial, Reprocessed	B	2a	2	1	N	N
76079	Catheter, Suprapubic (And Accessories)	B	3	2	2	Y	N
76080	Catheter, Upper Urinary Tract	B	2a	2	2	N	N
76081	Catheter, Ureteral Disposable (X-Ray)	B	2a	2	2	N	N
76082	Catheter, Ureteral, Gastro-Urology	B	2a	2	2	N	N
76083	Catheter, Ureteral, General & Plastic Surgery	B	2a	2	2	N	N
76084	Catheter, Urethral	B	2a	2	2	N	N
76085	Catheter, Urethrographic, Male	D	3	2	2	N	N
76086	Catheter, Urological	B	2a	2	2	N	N
76087	Catheter, Urological (Antimicrobial) And Accessories	B	2a	2	2	N	N
76088	Cement, Stomal Appliance, Ostomy	D	3	1	1	N	N
76089	Chair, Dialysis, Powered, Without Scales	D	3	1	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76090	Chair, Dialysis, Unpowered, Without Scales	A	1	1	1	N	N
76091	Choledochoscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76092	Clamp, Cannula	A	1	1	1	Y	N
76093	Clamp, Dialysis Arm	A	1	1	1	N	N
76094	Clamp, Electrical	B	2a	2	2	N	N
76095	Clamp, Line	A	1	1	1	N	N
76096	Clamp, Non-Electrical	D	3	1	1	N	N
76097	Clamp, Penile	A	1	1	1	N	N
76098	Clamp, Tubing, Blood, Automatic	C	2b	3	2	N	Y
76099	Collector, Ostomy	A	1	1	1	N	N
76100	Collector, Urine, (And Accessories) For Indwelling Catheter	A	1	1	2	N	N
76101	Collector, Urine, Pediatric, For Indwelling Catheter	A	1	1	2	N	N
76102	Collector, Urine, Powered, Non Indwelling Catheter	A	3	1	1	N	N
76103	Colonic Irrigation System	B	2a	2	2	N	N
76104	Colonic Irrigation System, General Well Being	B	2a	2	3	N	N
76105	Colonoscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76106	Colonoscope, General & Plastic Surgery	B	2a	2	2	N	N
76107	Confocal Optical Imaging	C	2b	3	2	N	N
76108	Connector, Blood Tubing, Infusion T	B	2a	2	2	N	Y
76109	Connector, Shunt	B	2a	2	1	N	N
76110	Connector, Tubing, Dialysate	B	2a	2	2	N	Y
76111	Connector, Ureteral Catheter	A	1	1	1	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76112	Container, Transport, Kidney	B	2a	2	2	N	N
76113	Cooler, Esophageal And Gastric	C	2b	3	3	N	N
76114	Cooler, Prostatic	C	2b	3	3	N	N
76115	Cord, Electric For Transurethral Surgical Instrument	B	2a	2	2	N	N
76116	Cord, Electric, For Endoscope	B	2a	2	2	N	N
76117	Cover, Biopsy Forceps	A	1	1	1	N	N
76118	Crusher, Spur, Colostomy	A	1	1	1	N	N
76119	Cushion, Hemorrhoid	B	2a	2	U	N	N
76120	Cystometer, Electrical Recording	B	2a	2	2	N	N
76121	Cystometric Gas (Carbon-Dioxide) On Hydraulic Device	B	2a	2	2	N	N
76122	Cystoscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76123	Cystourethroscope	B	2a	2	2	N	N
76124	Declotting Tray, Kit (Including Contents)	B	2a	2	2	N	N
76125	Desiccator, Transurethral	C	2b	3	2	N	N
76126	Detector, Air Bubble	C	2b	3	2	N	Y
76127	Detector, Air Or Foam	C	2b	3	2	N	Y
76128	Detector, Blood Level	C	2b	3	2	N	Y
76129	Detector, Dialysate Level	C	2b	3	2	N	Y
76130	Detector, Leak, Blood	C	2b	3	2	N	Y
76132	Device, Cystometric, Air	B	2a	2	3	N	N
76133	Device, Cystometric, Hydraulic	B	2a	2	2	N	N
76134	Device, Erectile Dysfunction	A	1	1	U	N	N
76135	Device, External Penile Rigidity	C	2b	3	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76136	Device, Impotence, Mechanical/Hydraulic	C	2b	3	3	Y	N
76137	Device, Incontinence, Mechanical/Hydraulic	C	2b	3	3	Y	N
76138	Device, Incontinence, Urosheath Type, Non-Sterile	A	1	1	1	N	N
76139	Device, Incontinence, Urosheath Type, Sterile	A	1	1	1	N	N
76140	Device, Locking, For Intestinal Clamp	A	1	1	1	N	N
76141	Device, Measuring, For Panendoscope	A	1	1	1	N	N
76142	Device, Paste-On For Incontinence, Non-Sterile	D	3	1	1	N	N
76143	Device, Paste-On For Incontinence, Sterile	A	1	1	1	N	N
76144	Device, Telemedicine, Robotic	C	2b	3	2	N	N
76145	Device, Thermal, Hemorrhoids	B	2a	2	U	N	N
76146	Device, Ultrasonic, Thermal Ablation	C	2b	3	3	N	N
76147	Device, Urine Flow Rate Measuring, Non-Electrical, Disposable	A	1	1	2	N	N
76148	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)	B	2a	2	2	N	Y
76149	Dialyzer, Capillary, Hollow Fiber	C	2b	3	2	N	Y
76150	Dialyzer, Disposable	C	2b	3	2	N	Y
76151	Dialyzer, High Permeability With Or Without Sealed Dialysate System	C	2b	3	2	N	Y
76152	Dialyzer, Parallel Flow	C	2b	3	2	N	Y
76153	Dialyzer, Single Coil	C	2b	3	2	N	Y
76154	Dialyzer, Twin Coil	C	2b	3	2	N	Y
76155	Dilator, Catheter, Ureteral	B	2a	2	2	N	N
76156	Dilator, Esophageal	B	2a	2	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76157	Dilator, Esophageal (Metal Olive) Gastro-Urology	B	2a	2	2	N	N
76158	Dilator, Rectal	B	2a	2	1	N	N
76159	Dilator, Urethral	B	2a	2	2	N	N
76160	Dilator, Urethral, Mechanical	B	2a	2	2	N	N
76161	Dilator, Vessel	B	2a	2	2	N	N
76162	Disinfectant, Dialysate Delivery System	B	2a	2	2	N	N
76163	Disinfectant, Subsystem, Water Purification	C	2b	3	2	N	N
76164	Dislodger, Stone, Basket, Ureteral, Metal	B	2a	2	2	N	N
76165	Dislodger, Stone, Basket, Ureteral, Metal, Reprocessed	B	2a	2	2	N	N
76166	Dislodger, Stone, Biliary	B	2a	2	2	N	N
76167	Dislodger, Stone, Flexible	B	2a	2	2	N	N
76168	Dislodger, Stone, Flexible, Ureteral, Reprocessed	B	2a	2	2	N	N
76169	Dissolvable Gel For Preventing Ureteral Stone Migration	C	2b	3	2	N	N
76170	Duodenoscope And Accessories, Flexible/Rigid	B	3	2	2	N	N
76171	Electrical Stimulation Bladder System	C	3	3	f	Y	N
76172	Electrode, Electrosurgical, Active, Urological	B	3	2	2	N	N
76173	Electrode, Electrosurgical, Active, Urological, Reprocessed	B	3	2	2	N	N
76174	Electrode, Flexible Suction Coagulator	B	3	2	2	N	N
76175	Electrode, Flexible Suction Coagulator, Reprocessed	B	3	2	2	N	N
76176	Electrode, Ph, Stomach	B	3	2	1	N	N
76177	Electrosurgical, Electrode Kit	B	3	2	2	N	N
76178	Endoilluminator	B	3	2	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76179	Endoilluminator, Reprocessed	B	3	2	2	N	N
76180	Endoscope And/Or Accessories	B	2a	2	2	N	N
76181	Endoscope Channel Accessory	B	3	2	2	N	N
76182	Endoscope Holder	B	3	2	2	N	N
76183	Endoscope, Ac-Powered And Accessories	B	3	2	2	N	N
76184	Endoscope, Battery-Powered And Accessories	B	3	2	2	N	N
76185	Endoscope, Fiber Optic	B	3	2	2	N	N
76186	Endoscope, Flexible	B	3	2	2	N	N
76187	Endoscope, Mirror	B	3	2	2	N	N
76188	Endoscope, Ophthalmic	D	3	2	2	N	N
76189	Endoscope, Prism	B	3	2	2	N	N
76190	Endoscope, Rigid	B	3	2	2	N	N
76191	Endoscopic Access Overtube, Gastroenterology-Urology	B	3	2	2	N	N
76192	Endoscopic Bite Block	A	3	1	1	N	N
76193	Endoscopic Central Control Unit	B	3	2	2	N	N
76194	Endoscopic Contamination Prevention Sheath	B	3	2	2	N	N
76195	Endoscopic Cytology Brush	B	2a	2	2	N	N
76196	Endoscopic Grasping/Cutting Instrument, Non-Powered	B	2a	2	2	N	N
76197	Endoscopic Guidewire, Gastroenterology-Urology	B	2a	2	2	N	N
76198	Endoscopic Injection Needle, Gastroenterology-Urology	B	2a	2	2	N	N
76199	Endoscopic Irrigation/Suction System	B	3	2	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76200	Endoscopic Retrograde Cholangiopancreatography (Ercp) Cannula	B	2a	2	2	N	N
76201	Endoscopic Storage Cover	B	2a	2	2	N	N
76202	Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (Gerd)	B	2a	2	2	Y	N
76203	Endoscopic Tissue Approximation Device	C	2b	3	2	N	N
76204	Endoscopic Ultrasound System, Gastroenterology-Urology	B	2a	2	2	N	N
76205	Endoscopic Video Imaging System/Component, Gastroenterology-Urology	A	1	1	2	N	N
76206	Endoscopic Magnetic Retriever	B	2a	2	2	N	N
76207	Enema Kit, (For Cleaning Purpose)	B	2a	2	1	N	N
76208	Enteroscope And Accessories	B	2a	2	2	N	N
76209	Equipment, Photographic, For Physiologic Function Monitor	B	2a	2	1	N	N
76210	Esophagoscope, General & Plastic Surgery	B	2a	2	2	N	N
76211	Esophagoscope, Rigid, Gastro-Urology	B	2a	2	2	N	N
76212	Evacuator, Bladder, Manually Operated	B	2a	2	1	N	N
76213	Evacuator, Gastro-Urology	B	2a	2	2	N	N
76214	External Urethral Occluder, Urinary Incontinence-Control, Female	B	2a	2	1	N	N
76215	Filiform And Filiform Follower	B	2a	2	1	N	N
76216	Filter, Blood, Dialysis	B	2a	2	2	N	Y
76217	Flowmeter, Dialysate	C	2b	3	2	N	Y
76218	Forceps, Biopsy, Electric	B	2a	2	2	N	N
76219	Forceps, Biopsy, Electric, Reprocessed	B	2a	2	2	N	N

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76220	Forceps, Biopsy, Non-Electric	B	2a	2	1	N	N
76221	Forceps, Biopsy, Non-Electric, Reprocessed	B	2a	2	1	N	N
76222	Forceps, Disconnect	A	1	1	1	N	N
76223	Garment, Protective, For Incontinence	A	1	1	1	N	N
76224	Gastrointestinal Motility System, Capsule	C	2b	3	U	N	N
76225	Gastroscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76226	Gastroscope, General & Plastic Surgery	B	2a	2	2	N	N
76227	Graft, Vascular, Hemodialysis Access, Synthetic/Biological Composite	C	2b	3	3	N	N
76228	Guard, Shunt	A	1	1	2	N	N
76229	Gun, Tie, Dialysis	A	1	1	1	N	N
76230	Hemodialysis System For Home Use	C	2b	3	2	N	N
76231	Hemodialyzer, High Cut-Off	C	2b	3	U	N	N
76232	Hemodialyzer, Re-Use, High Flux	C	2b	3	2	N	Y
76233	Hemodialyzer, Re-Use, Low Flux	C	2b	3	2	N	Y
76234	Holder, Needle, Gastroenterologic	A	1	1	1	N	N
76235	Holder, Ureteral Catheter	A	1	1	1	N	N
76236	Hook, Gastro-Urology	A	1	1	1	N	N
76237	Image, Illumination, Fiberoptic, For Endoscope	A	1	1	2	N	N
76238	Implant, Anti-Gastroesophageal Reflux	C	2b	3	3	Y	N
76239	Implant, Intra-gastric For Morbid Obesity	C	2b	3	3	Y	N
76240	Implantable Bladder-Evacuation Electrical Stimulation System	C	2b	3	f	Y	N
76241	Implanted Fecal Incontinence Device	C	2b	3	3	Y	N
76242	Insert, Pump, Blood	A	1	1	2	N	Y

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76243	Instrument, Biopsy	B	2a	2	2	N	N
76244	Instrument, Biopsy, Mechanical, Gastrointestinal	B	2a	2	2	N	N
76245	Instrument, Biopsy, Reprocessed	B	2a	2	2	N	N
76246	Instrument, Biopsy, Suction	B	2a	2	2	N	N
76247	Instrument, Catheter, Punch	A	1	1	1	N	N
76248	Instrument, Special Lens, For Endoscope	A	1	1	1	N	N
76249	Insufflator, Automatic Carbon-Dioxide For Endoscope	B	2a	2	2	N	N
76250	Intestinal Splinting Tubes	B	2a	2	2	N	N
76252	Intracatheter, Dialysis	C	2b	3	2	N	Y
76253	Irrigator, Ostomy	B	2a	2	2	N	N
76254	Jelly, Contact, For Transurethral Surgical Instrument	B	2a	2	2	N	N
76255	Jelly, Lubricating, For Transurethral Surgical Instrument	B	2a	2	2	N	N
76256	Kit, Catheter, Cystostomy, Suprapubic	D	2a	2	2	N	N
76257	Kit, Catheter, External, Male (Excludes Hiv Testing)	D	2a	2	2	N	N
76258	Kit, Catheter, Foley (Excludes Hiv Testing)	D	2a	2	2	N	N
76259	Kit, Catheter, Urinary (Excludes Hiv Testing)	D	2a	2	2	N	N
76260	Kit, Cholangiogram, Endoscopic	D	2a	2	2	N	N
76261	Kit, Choledochoscope, Flexible And Rigid	D	2a	2	2	N	N
76262	Kit, Introducer, Endoscope	D	2a	2	2	N	N
76263	Kit, Nephroscope	D	2a	2	2	N	N
76264	Kit, Repair, Catheter, Hemodialysis	B	2a	2	2	N	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76265	Lamp, Endoscope, Incandescent	A	1	1	2	N	N
76266	Laparoscope, General & Plastic Surgery	B	2a	2	2	N	N
76267	Laparoscope, General & Plastic Surgery, Reprocessed	B	2a	C	2	N	N
76268	Laparoscopic Single Port Access Device	B	2a	2	2	N	N
76269	Laparoscopy Kit	B	2a	2	2	N	N
76270	Laryngoscope, Endoscope	B	2a	2	2	N	N
76271	Laser For Gastro-Urology Use	C	2b	3	U	N	N
76272	Led Light Source	B	2a	2	2	N	N
76273	Ligator, Esophageal	B	2a	2	2	N	N
76274	Ligator, Hemorrhoidal	B	2a	2	2	N	N
76275	Light Source System, Diagnostic Endoscopic	C	2b	3	3	N	N
76276	Light Source, Endoscope, Xenon Arc	B	2a	2	2	N	N
76277	Light Source, Fiberoptic, Routine	A	1	1	2	N	N
76278	Light Source, Incandescent, Diagnostic	A	1	1	2	N	N
76279	Light Source, Photographic, Fiberoptic	A	1	1	2	N	N
76280	Light, Catheter, Fiberoptic, Glass, Ureteral	B	2a	2	2	N	N
76281	Lithotripter, Shockwave (For Treating Gallbladder Stones)	C	2b	3	3	N	N
76282	Lithotripter, Biliary Mechanical	A	1	1	2	N	N
76283	Lithotripter, Electro-Hydraulic	C	2b	3	2	N	N
76285	Lithotripter, Ultrasonic	C	2b	3	U	N	N
76286	Magnet, Continent Colostomy	C	2b	3	U	N	N
76287	Manometer, Water	A	1	1	2	N	N
76288	Marker, Colon	C	2b	3	U	N	N
76289	Media, Culture, Ex Vivo, Tissue And Cell	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76290	Mediastinoscope, Diagnostic	B	2a	2	2	N	N
76291	Meter, Conductivity, Induction, Remote Type	B	2a	2	2	N	N
76292	Meter, Conductivity, Non-Remote	B	2a	2	2	N	Y
76293	Mini Endoscope, Gastroenterology-Urology	B	2a	2	2	N	N
76294	Monitor, Esophageal Motility, And Tube	B	2a	2	2	N	N
76295	Monitor, Penile Tumescence	B	2a	2	U	N	N
76296	Monitor, Temperature, Dialysis	C	2b	3	2	N	Y
76297	Needle And Needle Set, Gastro-Urology, Reprocessed	B	2a	2	2	N	N
76298	Needle, Endoscopic, Reprocessed	B	2a	2	2	N	N
76299	Needle, Fistula	B	2a	2	2	N	N
76300	Needle, Fistula, Reprocessed	B	2a	2	2	N	N
76301	Needle, Pneumoperitoneum, Simple	B	2a	2	2	N	N
76302	Needle, Pneumoperitoneum, Spring Loaded, Reprocessed	B	2a	2	2	N	N
76303	Obturator, For Endoscope	B	2a	2	2	N	N
76304	Oral Removable Retainer For Weight Loss	B	2a	2	U	N	N
76305	Orchidometer	A	1	1	1	N	N
76306	Pacemaker, Bladder	C	2b	3	3	Y	N
76307	Pancreatoscope, Biliary	B	2a	2	2	N	N
76308	Panendoscope (Gastroduodenoscope)	B	2a	2	2	N	N
76309	Panendoscope (Urethroscope)	B	2a	2	2	N	N
76310	Peritoneal Dialysate Filter	B	2a	2	2	N	Y
76311	Peritoneoscope	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76312	Ph Meter For Dialysis Hydrogen Ion Concentration	B	2a	2	2	N	Y
76313	Pill, Radio	C	2b	3	U	N	N
76314	Plate, Patient	C	2b	3	2	N	N
76315	Plier, Crimp	A	1	1	1	N	N
76316	Plier, Tube	A	1	1	1	N	N
76317	Pneumoperitoneum Needle	B	2a	2	2	N	N
76318	Pouch, Colostomy	A	1	1	1	N	N
76319	Probe And Director, Gastro-Urology	A	1	1	1	N	N
76320	Probe, Rectal, Non-Powered	A	1	1	1	N	N
76321	Proctoscope	B	2a	2	2	N	N
76322	Prostate Lesion, Documentation, System	B	2a	2	2	N	N
76323	Prosthesis, Penile	C	2b	3	2	Y	N
76324	Prosthesis, Penis, Inflatable	C	2b	3	3	Y	N
76325	Prosthesis, Penis, Rigid Rod	C	2b	3	2	Y	N
76326	Prosthesis, Testicle	C	2b	3	3	Y	N
76327	Prosthesis, Testicular	C	2b	3	3	Y	N
76328	Prosthesis, Urethral Sphincter	C	2b	3	3	Y	N
76329	Prosthesis, Vas Deferans	C	2b	3	3	Y	N
76330	Protector, Ostomy	A	1	1	1	N	N
76331	Protector, Transducer, Dialysis	B	2a	2	2	N	Y
76332	Pump, Air, Non-Manual, For Endoscope	B	2a	2	2	N	N
76333	Pump, Blood, Extra-Luminal	B	2a	2	2	N	Y
76334	Pump, Infusion Or Syringe, Extra-Luminal	C	2b	3	2	N	Y
76335	Punch, Biopsy	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76336	Recorder, External, Pressure, Amplifier & Transducer	B	2a	2	2	N	N
76337	Replacer, Ureteral	C	2b	3	3	Y	N
76338	Replacer, Urethral	C	2b	3	3	Y	N
76339	Resectoscope	B	2a	2	2	N	N
76340	Resectoscope, Working Element	B	2a	2	2	N	N
76341	Retractor, Fiberoptic	A	1	1	1	N	N
76342	Retractor, Non-Self-Retaining	A	1	1	1	N	N
76343	Retractor, Self-Retaining	A	1	1	1	N	N
76344	Ribdam	A	1	1	1	N	N
76345	Ring, Crimp	A	1	1	1	N	N
76346	Ring, Joint	A	1	1	1	N	N
76347	Ring, Laparotomy	A	1	1	1	N	N
76348	Rod, Colostomy	A	1	1	2	N	N
76349	Rongeur, Cystoscopic	A	1	1	2	N	N
76350	Rongeur, Cystoscopic, Hot	B	2a	2	2	N	N
76351	Scissors For Cystoscope	A	1	1	2	N	N
76352	Scoop	A	1	1	1	N	N
76353	Selector, Size, Ostomy	A	1	1	1	N	N
76354	Set, Administration, For Peritoneal Dialysis, Disposable	B	2a	2	2	N	Y
76355	Set, Dialysis, Single Needle (Co-Axial Flow)	B	2a	2	3	Y	N
76356	Set, Dialysis, Single Needle With Uni-Directional Pump	B	2a	2	2	N	Y
76357	Set, Dialysis, Single Needle With Uni-Directional Pump, Reprocessed	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76358	Set, Dialyzer Holder	B	2a	2	2	N	N
76359	Set, Gavage, Infant, Sterile	B	2a	2	2	N	N
76360	Set, Perfusion, Kidney, Disposable	B	2a	2	2	N	N
76361	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve	B	2a	2	2	N	Y
76362	Sheath, Corrugated Rubber, For Non-Indwelling Catheter, Non-Sterile	A	1	1	1	N	N
76363	Sheath, Corrugated Rubber, For Nonindwelling Catheter, Sterile	A	1	1	1	N	N
76364	Shunt, Peritoneal	C	2b	3	2	Y	N
76365	Sigmoidoscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76366	Sigmoidoscope, Rigid, Electrical	B	2a	2	2	N	N
76367	Sigmoidoscope, Rigid, Non-Electrical	B	2a	2	2	N	N
76368	Snare, Flexible	B	2a	2	2	N	N
76369	Snare, Flexible, Reprocessed	B	2a	2	2	N	N
76370	Snare, Non-Electrical	A	1	1	1	N	N
76371	Snare, Rigid Self-Opening	A	1	1	2	N	N
76372	Solution, Sodium Hyaluronate	C	2b	3	3	N	N
76373	Solution-Test Standard-Conductivity, Dialysis	B	2a	2	2	N	N
76374	Sound, Metal, Interconnected	A	1	1	1	N	N
76375	Sound, Urethral, Metal Or Plastic	B	2a	2	1	N	N
76376	Speculum, Rectal	A	1	1	1	N	N
76377	Sphincteroscope	B	2a	2	2	N	N
76378	Spreader, Bladder Neck	A	1	1	1	N	N
76379	Stabilizer, Shunt	A	1	1	2	N	N
76380	Station, Dialysis Control, Negative Pressure Type	C	2b	3	2	N	Y

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76381	Stent, Ureteral	C	2b	3	2	Y	N
76382	Stent, Urethral, Bulbous, Permanent Or Semi-Permanent	C	2b	3	3	N	N
76383	Stent, Urethral, Prostatic, Permanent Or Semi-Permanent	C	2b	3	3	N	N
76384	Stent, Urethral, Prostatic, Semi-Permanent	C	2b	3	3	N	N
76385	Stent,Urethral,External Sphincter,Permanent	C	2b	3	3	Y	N
76386	Stimulator, Electrical For Sperm Collection	C	2b	3	U	N	N
76387	Stimulator, Electrical, Implantable, For Incontinence	C	2b	3	3	Y	N
76388	Stimulator, Electrical, Non-Implantable, For Incontinence	B	2a	2	2	N	N
76389	Stimulator,Bladder	C	2b	3	f	N	N
76390	Stimulator,Peripheral Nerve,Non-Implanted,For Pelvic Floor Dysfunction	B	2a	2	2	N	N
76391	Stirrups	A	1	1	1	N	N
76392	String And Tubes, Gastrointestinal, To Locate Internal Bleeding	B	2a	2	2	N	N
76393	Strip, Dialysate Ph Indicator	B	2a	2	2	N	N
76394	Strip, Dialysate, Ph, Bicarbonate, Glucose, Acid, Indicator	C	2b	3	2	N	N
76395	Strip, Test, Reagent, Residuals For Dialysate, Disinfectant	B	2a	2	2	N	N
76396	Stylet For Catheter, Gastro-Urology	B	2a	2	1	N	N
76397	Stylet, Ureteral	A	1	1	1	N	N
76398	Subsystem, Proportioning	C	2b	3	2	N	Y

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876 GASTROENTEROLOGY-UROLOGY DEVICES							
76399	Subsystem, Water Purification	C	2b	3	2	N	N
76400	Support, Hernia	A	1	1	1	N	N
76401	Surgical Instruments, G-U, Manual (And Accessories)	A	1	1	1	N	N
76402	System Accessories, Extracorporeal	B	2a	2	2	N	Y
76403	System And Accessories, Isolated Heart, Transport And Preservation	C	2b	3	2	N	N
76404	System, Alarm, Electrosurgical	B	2a	2	2	N	N
76405	System, Blood, Extracorporeal And Accessories	B	2a	2	2	N	Y
76406	System, Dialysate Delivery, Central Multiple Patient	C	2b	3	2	N	Y
76407	System, Dialysate Delivery, Recirculating	C	2b	3	2	N	Y
76408	System, Dialysate Delivery, Recirculating, Single Pass	C	2b	3	2	N	Y
76409	System, Dialysate Delivery, Sealed	C	2b	3	2	N	Y
76410	System, Dialysate Delivery, Semi-Automatic, Peritoneal	C	2b	3	2	N	Y
76411	System, Dialysate Delivery, Single Pass	C	2b	3	2	N	Y
76412	System, Dialysate Delivery, Single Patient	C	2b	3	2	N	Y
76413	System, Dialysate Delivery, Sorbent Regenerated	C	2b	3	2	N	Y
76414	System, Evacuator, Fluid	B	2a	2	2	N	N
76415	System, Gastrointestinal Motility (Electrical)	B	2a	2	2	N	N
76416	System, Hemodialysis, Access Recirculation Monitoring	C	2b	3	2	N	Y
76417	System, Hemodialysis, Remote Accessories	B	2a	2	1	N	N
76418	System, Imaging, Esophageal, Wireless, Capsule	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76419	System, Imaging, Gastrointestinal, Wireless, Capsule	B	2a	2	2	N	N
76420	System, Irrigation, Urological	B	2a	2	U	N	N
76421	System, Perfusion, Kidney	B	2a	2	2	N	N
76422	System, Peritoneal, Automatic Delivery	C	2b	3	2	N	Y
76423	System, Urine Drainage, Closed, For Non-Indwelling Catheter, Non-Sterile	A	1	1	1	N	N
76424	System, Urine Drainage, Closed, For Nonindwelling Catheter, Sterile	A	1	1	1	N	N
76425	System, Water Jet Catheter, Renal	B	2a	2	2	N	N
76426	System, Water Purification, General Medical Use	C	2b	3	2	N	N
76426	System, Water Purification, General Medical Use	C	2b	3	2	N	N
76427	System,Electrogastrography(Egg)	B	2a	2	2	N	N
76428	System,Surgical,Computer Controlled Instrument	C	2b	3	2	N	N
76429	Table, Cysto, Non-Electrical	A	1	1	1	N	N
76430	Table, Cystometric, Electric	B	2a	2	2	N	N
76431	Table, Cystometric, Non-Electric And Accessories	A	1	1	1	N	N
76432	Tank, Holding, Dialysis	B	2a	2	2	N	N
76433	Telescope, Rigid, Endoscopic	B	2a	2	2	N	N
76434	Tie, Dialysis	A	1	1	1	N	N
76435	Tip, Vessel	C	2b	3	3	Y	N
76436	Transformer, Endoscope	B	2a	2	2	N	N
76437	Transurethral Electrosurgical Unit, Benign Prostatic Hyperplasia	C	2b	3	2	N	N
76438	Transurethral Occlusion Insert, Urinary Incontinence-Control, Female	C	2b	3	3	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76439	Tray, Biopsy, Without Biopsy Instruments	a	1	1	1	N	N
76440	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (Kit)	B	2a	2	2	N	N
76441	Tray, Irrigation, Sterile	B	2a	2	2	N	N
76442	Tray, Start/Stop (Including Contents), Dialysis	B	2a	2	1	N	N
76443	Tray, Surgical, Needle	B	2a	2	U	N	N
76444	Tripsor, Stone, Bladder	B	2a	2	2	N	N
76445	Trocar, Gastro-Urology	B	2a	2	2	N	N
76446	Truss, Umbilical	A	1	1	1	N	N
76447	Tube, Double Lumen For Intestinal Decompression And/Or Intubation	B	2a	2	2	N	N
76448	Tube, Drainage, Suprapubic	B	2a	2	2	N	N
76449	Tube, Feeding	B	2a	2	2	N	N
76450	Tube, Gastro-Enterostomy	B	2a	2	2	N	N
76451	Tube, Levine	B	2a	2	2	N	N
76452	Tube, Nasogastric	B	2a	2	2	N	N
76453	Tube, Single Lumen, W Mercury Wt Balloon For Intes. Intub. &/Or Decompression	B	2a	2	2	N	N
76454	Tube, Smoke Removal, Endoscopic	B	2a	2	1	N	N
76455	Tubes, Gastrointestinal (And Accessories)	B	2a	2	2	N	N
76456	Tubing, Dialysate	B	2a	2	2	N	Y
76457	Tubing, Dialysate (And Connector)	B	2a	2	2	N	Y
76458	Unit, Electrosurgical	C	2b	3	2	N	N
76459	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
876 GASTROENTEROLOGY-UROLOGY DEVICES							
76460	Unit, Electrosurgical, Endoscopic (With Or Without Accessories), Reprocessed	C	2b	3	2	N	N
76461	Ureteroscope And Accessories, Flexible/Rigid	B	2a	2	2	N	N
76462	Urethrometer	B	2a	2	1	N	N
76463	Urethroscope	B	2a	2	2	N	N
76464	Urethrotome	A	1	1	2	N	N
76465	Urinary Drainage Collection Kit, For Indwelling Catheter	A	1	1	2	N	N
76466	Urinometer, Electrical	B	2a	2	2	N	N
76467	Urinometer, Mechanical	A	1	1	2	N	N
76468	Uroflowmeter	B	2a	2	2	N	N
76469	Valve, Ureterovesicle	C	2b	3	3	Y	N
76470	Warmer, Peritoneal Dialysate	B	2a	2	2	N	Y
76471	Washer, Cleaner, Automated, Endoscope	B	2a	2	2	N	N
76472	Water-Induced Thermoerapy System, Benign Prostatic Hyperplasia	C	2b	3	2	N	N
76473	Wristlet, Patient Return	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78001	Accessories, Catheter	B	2a	2	1	N	N
78002	Accessories, Operating-Room, Table (Kit)	A	1	1	1	N	N
78003	Accessory, Surgical Apparel	A	1	1	1	N	N
78004	Adaptor, Catheter	B	2a	2	1	N	N
78005	Agent, Absorbable Hemostatic, Collagen Based	D	3	4	3	Y	N
78006	Agent, Absorbable Hemostatic, Non-Collagen Based	C	2b	3	3	Y	N
78007	Air Filter Portable Apparatus	B	2a	2	2	N	N
78008	Anchor, Fascial	B	2a	2	2	Y	N
78009	Apparatus, Air Handling, Bench	A	1	1	2	N	N
78010	Apparatus, Air Handling, Enclosure	A	1	1	2	N	N
78011	Apparatus, Air Handling, Room	A	1	1	2	N	N
78012	Apparatus, Electrosurgical	C	2b	3	2	N	N
78013	Apparatus, Exhaust, Surgical	A	1	1	2	N	N
78014	Apparatus, Suction, Single Patient Use, Portable, Nonpowered	B	2a	2	1	N	N
78015	Apparatus, Suction, Ward Use, Portable, Ac-Powered	B	2a	2	2	N	N
78016	Apparatus, Suturing, Stomach And Intestinal	A	1	1	1	N	N
78017	Appliance, Facial Fracture, External	A	1	1	1	N	N
78018	Applicator, Transurethral, Radio Frequency, For Stress Urinary Incontinence In Women	B	2a	2	2	N	N
78019	Applier, Hemostatic Clip	B	2a	2	1	N	N
78020	Applier, Staple, Surgical,	A	1	1	1	N	N
78021	Applier, Surgical, Clip	B	2a	2	1	N	N
78022	Aspiration Tray (Kit)	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78023	Bag, Intestine	B	2a	2	1	N	N
78024	Battery, Replacement, Rechargeable	B	2a	2	1	N	N
78025	Beads, Hydrophilic, For Wound Exudate Absorption	A	1	1	1	N	N
78026	Biospy Device, Percutaneous, Reprocessed	B	2a	2	1	N	N
78027	Bit, Surgical	B	2a	2	1	N	N
78028	Blade, Saw, General & Plastic Surgery, Surgical	B	2a	2	1	N	N
78029	Blade, Saw, Surgical, Cardiovascular	B	2a	2	1	N	N
78030	Blade, Scalpel	B	2a	2	1	N	N
78031	Board, Arm (With Cover), Sterile	A	1	1	1	N	N
78032	Board, Arm (With Cover), Non-Sterile	D	3	1	1	N	N
78033	Body Fluid Barrier Kit	B	2a	2	2	N	N
78034	Body Fluid Clean Up Kit	B	2a	2	2	N	N
78035	Body Fluid Disposal Kit	B	2a	2	2	N	N
78036	Booth, Sun Tan	A	1	1	1	N	N
78037	Bronchial Thermoplasty System	C	2b	3	3	N	N
78038	Brush, Biopsy, General & Plastic Surgery	B	2a	2	1	N	N
78039	Brush, Dermabrasion, Manual	B	2a	2	1	N	N
78040	Brush, Dermabrasion, Powered	B	2a	2	1	N	N
78041	Brush, Scrub, Operating-Room	B	2a	2	1	N	N
78042	Bur, Surgical, General & Plastic Surgery	B	2a	2	1	N	N
78043	Cabinet, Phototherapy (Puva)	B	2a	2	2	N	N
78044	Camera, Cine, Endoscopic, With Audio	B	2a	2	1	N	N
78045	Camera, Cine, Endoscopic, Without Audio	B	2a	2	1	N	N
78046	Camera, Cine, Microsurgical, With Audio	B	2a	2	1	N	N
78047	Camera, Cine, Microsurgical, Without Audio	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78048	Camera, Cine, Surgical, With Audio	B	2a	2	1	N	N
78049	Camera, Cine, Surgical, Without Audio	B	2a	2	1	N	N
78050	Camera, Still, Endoscopic	A	1	1	1	N	N
78051	Camera, Still, Microsurgical	A	1	1	1	N	N
78052	Camera, Still, Surgical	A	1	1	1	N	N
78053	Camera, Surgical And Accessories	A	1	1	1	N	N
78054	Camera, Television, Endoscopic, With Audio	B	2a	2	1	N	N
78055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	1	N	N
78056	Camera, Television, Microsurgical, With Audio	A	1	1	1	N	N
78057	Camera, Television, Microsurgical, Without Audio	A	1	1	1	N	N
78058	Camera, Television, Surgical, With Audio	D	3	1	1	N	N
78059	Camera, Television, Surgical, Without Audio	A	1	1	1	N	N
78060	Cannula, Ear	A	1	1	1	N	N
78061	Cannula, Injection	B	2a	2	1	N	N
78062	Cannula, Sinus	B	2a	2	1	N	N
78063	Cannula, Surgical, General & Plastic Surgery	D	3	2	1	N	N
78064	Cannulae, Bronchial	B	2a	2	1	N	N
78065	Cap, Surgical	A	1	1	1	N	N
78066	Carrier, Ligature	A	1	1	1	N	N
78067	Cassette, Audio Tape	A	1	1	U	N	N
78068	Catheter, Balloon Type	B	2a	2	1	N	N
78069	Catheter, Cholangiography	B	2a	2	1	N	N
78070	Catheter, Continuous Irrigation	B	2a	2	1	N	N
78071	Catheter, Drainage, Intraoral/Extraoral	B	2a	2	1	N	N
78072	Catheter, Eustachian, General & Plastic Surgery	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78073	Catheter, Infusion	B	2a	2	1	N	N
78074	Catheter, Irrigation	B	2a	2	1	N	N
78075	Catheter, Multiple Lumen	B	2a	2	1	N	N
78076	Catheter, Nephrostomy, General & Plastic Surgery	B	2a	2	1	N	N
78077	Catheter, Pediatric, General & Plastic Surgery	B	2a	2	1	N	N
78078	Catheter, Peritoneal	B	2a	2	1	N	N
78079	Catheter, Ventricular, General & Plastic Surgery	B	3	2	1	N	N
78080	Cement Obturator	B	2a	2	2	Y	N
78081	Chair, Surgical, Ac-Powered	A	1	1	1	N	N
78082	Chair, Surgical, Non-Electrical	A	1	1	1	N	N
78083	Chamber, Oxygen, Topical, Extremity	B	2a	2	2	N	N
78084	Chisel (Osteotome)	A	1	1	1	N	N
78085	Chisel, Mastoid	D	3	1	1	N	N
78086	Chisel, Nasal	A	1	1	1	N	N
78087	Chisel, Surgical, Manual	A	1	1	1	N	N
78088	Clamp	D	3	1	1	N	N
78089	Clamp, Surgical, General & Plastic Surgery	D	3	1	1	N	N
78090	Clip, Hemostatic	C	2b	3	2	Y	N
78091	Clip, Implantable	C	2b	3	2	Y	N
78092	Clip, Implantable, For Coronary Artery Bypass Graft (Cabg)	D	3	4	2	Y	N
78093	Clip, Implantable, Reprocessed	C	2b	3	2	Y	N
78094	Clip, Removable (Skin)	B	2a	2	1	N	N
78095	Clip, Vas Deferens	C	2b	3	2	Y	N
78096	Closure, Wound, Adhesive	D	3	1	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78097	Composite Cultured Skin	C	2b	3	U	Y	N
78098	Connector, Catheter	B	2a	2	1	N	N
78099	Contractor, Surgical	A	1	1	1	N	N
78100	Cover, Barrier, Protective	B	2a	2	2	N	N
78101	Cover, Shoe, Operating-Room	A	1	1	1	N	N
78102	Cream, Gloving, Surgeon'S	A	3	1	1	N	N
78103	Cryogenic, Skin Tag Removal, Otc	A	1	1	2	N	N
78104	Cultured Epithelial Autograft	D	3	4	f	Y	Y
78105	Curette	B	2a	2	1	N	N
78106	Curette, Surgical, General Use	B	2a	2	1	N	N
78107	Cutaneous Tissue Adhesive With Mesh	A	1	1	2	N	N
78108	Cutter, Surgical	B	2a	2	1	N	N
78109	Degreaser, Skin, Surgical	A	1	1	1	N	N
78110	Dermal Cooling Pack/Vacuum/Massager	B	2a	2	2	N	N
78111	Dermatome	B	2a	2	1	N	N
78112	Device, Dermal Replacement	D	3	4	3	Y	N
78113	Device, Endoscopic Suturing	B	2a	2	U	N	N
78114	Device, Percutaneous, Biopsy	B	2a	2	1	N	N
78115	Dilator, Catheter	B	2a	2	1	N	N
78116	Dissector, Surgical, General & Plastic Surgery	B	2a	2	1	N	N
78117	Drainage Catheter With Antibiotic	C	2b	3	2	N	N
78118	Drape, Adhesive, Aerosol	A	1	1	1	N	N
78119	Drape, Microscope, Ophthalmic	A	1	1	2	N	N
78120	Drape, Patient, Ophthalmic	A	1	1	2	N	N
78121	Drape, Pure Latex Sheet, With Self-Retaining Finger Cot	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78122	Drape, Surgical	A	1	1	2	N	N
78123	Drape, Surgical, Ent	A	1	1	2	N	N
78124	Drape, Urological, Disposable	A	1	1	2	N	N
78125	Dress, Surgical	A	1	1	1	N	N
78126	Dressing Change Tray	A	1	1	N	N	N
78127	Dressing,Wound,Hydrogel W/Out Drug And/Or Biologic	B	2a	2	1	N	N
78128	Dressing,Wound,Hydrophilic	B	2a	2	1	N	N
78129	Dressing,Wound,Occlusive	B	2a	2	1	N	N
78130	Drill, Battery Powered, Subungual Hematoma	B	2a	2	1	N	N
78131	Driver, Surgical, Pin	A	1	1	1	N	N
78132	Elastomer, Silicone, For Scar Management	B	2a	2	1	N	N
78133	Electrode, Electrosurgical	C	2b	3	2	N	N
78134	Electrode, Gel, Electrosurgical	C	2b	3	2	N	N
78135	Electrosurgical Coagulation For Aesthetic	C	2b	3	2	N	N
78136	Electrosurgical Device	C	2b	3	2	N	N
78137	Electrosurgical Patient Return Electrode	C	2b	3	2	N	N
78138	Electrosurgical Radiofrequency System, Stress Urinary Incontinence, Female, Transvaginal Or Laparoscopic, Pelvic Tissue	C	2b	3	2	N	N
78139	Electrosurgical, Cutting & Coagulation & Accessories	C	2b	3	2	N	N
78140	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed	C	2b	3	2	N	N
78141	Elevator	D	3	1	1	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78142	Elevator, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78143	Emergency Response Safety Kit	B	2a	2	2	N	N
78144	Epilator, High Frequency, Needle-Type	B	2a	2	1	N	N
78145	Epilator, High Frequency, Tweezer-Type	B	2a	2	1	N	N
78146	Expander, Skin, Inflatable	C	2b	3	U	Y	N
78147	Expander, Surgical, Skin Graft	A	1	1	1	N	N
78148	Expander,Breast,External	C	2b	3	U	N	N
78149	Extractor, Vein	A	1	1	1	N	N
78150	Facial Implant	C	2b	3	2	Y	N
78151	Fat Reducing Low Level Laser	C	2b	3	2	N	N
78152	File, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78153	Film, Camera, Surgical	A	1	1	1	N	N
78154	First Aid Kit Without Drug	A	1	1	1	N	N
78155	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption	B	2a	2	2	N	N
78156	Forceps	A	1	1	1	N	N
78157	Forceps, General & Plastic Surgery	A	1	1	1	N	N
78158	Forceps, Wire Holding	A	1	1	1	N	N
78159	Frame, Camera, Surgical	A	1	1	1	N	N
78160	Gas, Laser Generating	B	2a	2	1	N	N
78161	Gauze/Sponge, Internal, X-Ray Detectable	B	2a	2	1	N	N
78162	Gauze/Sponge,Nonresorbable For External Use	A	1	1	1	N	N
78163	General Surgery Tray (Kit)	B	2a	2	2	N	N
78164	Generator,Electrosurgical,Coagulation,Cancer	C	2b	3	2	N	N
78165	Gouge, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78166	Gown, Isolation, Surgical	A	1	1	2	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78167	Gown, Patient	A	1	1	2	N	N
78168	Gown, Surgical	A	1	1	2	N	N
78169	Guard, Instrument	B	3	2	U	N	N
78170	Guard, Skin Graft	A	3	1	U	N	N
78171	Guide, Needle, Surgical	B	3	2	1	N	N
78172	Guide, Surgical, Instrument	B	3	2	1	N	N
78173	Hammer, Surgical	A	3	1	1	N	N
78174	Handle, Scalpel	A	3	1	1	N	N
78175	Head, Surgical, Hammer	A	3	1	1	N	N
78176	Helmet, Surgical	A	3	1	1	N	N
78177	Hemostat	A	3	1	1	N	N
78178	Holder, Camera, Surgical	A	3	1	1	N	N
78179	Holder, Ear Speculum	A	1	1	1	N	N
78180	Holder, Speculum, Ent	A	3	1	1	N	N
78181	Hood, Surgical	A	3	1	2	N	N
78182	Hook, Bone	A	3	1	1	N	N
78183	Hook, Surgical, General & Plastic Surgery	A	3	1	1	N	N
78184	Illuminator, Fiberoptic, Surgical Field	B	3	2	2	N	N
78185	Illuminator, Non-Remote	A	3	1	2	N	N
78186	Illuminator, Remote	A	3	1	2	N	N
78187	Implant, Collagen For Non-Aesthetic Use	D	3	3	3	Y	N
78188	Implant, Dermal, For Aesthetic Use	C	3	3	3	Y	N
78189	Implant, Malar	C	3	3	U	Y	N
78190	Implant, Muscle, Pectoralis	C	3	3	U	Y	N
78191	Implant, Temporal	C	3	3	2	Y	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78192	Inhibitor, Postoperative Fibrosis (Adhesion Barrier)	C	3	3	N	N	N
78193	Instrument For Treatment Of Hyperhidrosis	B	3	2	2	N	N
78194	Instrument, Cutting, Orthopedic	B	2a	2	1	N	N
78195	Instrument, Ligature Passing And Knot Tying	B	2a	2	1	N	N
78196	Instrument, Manual, Surgical, General Use	A	1	1	1	N	N
78197	Instrument, Surgical, Disposable	B	2a	2	1	N	N
78198	Instrument, Surgical, Orthopedic, Ac-Powered Motor And Accessory/Attachment	B	3	2	1	N	N
78199	Instrument, Ultrasonic Surgical	C	2b	3	U	N	N
78200	Isometer	B	2a	2	U	N	N
78201	Kit, First Aid, Talking	A	1	1	1	N	N
78202	Kit, I.V. Start	B	2a	2	U	N	N
78203	Kit, Plastic Surgery And Accessories	A	1	1	1	N	N
78204	Kit, Surgical Instrument, Disposable	B	2a	2	1	N	N
78205	Knife, Amputation	A	1	1	1	N	N
78206	Knife, Surgical	B	2a	2	1	N	N
78207	Label Or Tag, Sterile	A	1	1	1	N	N
78208	Lamp, Fluorescein, Ac-Powered	B	2a	2	2	N	N
78209	Lamp, Operating-Room	A	1	1	2	N	N
78210	Lamp, Surgical	A	1	1	2	N	N
78211	Lamp, Surgical, Incandescent	A	1	1	2	N	N
78212	Lancet, Blood	B	2a	2	1	N	N
78213	Laser Assisted Lipolysis	C	2b	3	2	N	N
78214	Laser, Benign Prostatic Hyperplasia	C	2b	3	2	N	N
78215	Laser, Cellulite Appearance	C	2b	3	2	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78216	Laser, Dental, Soft Tissue	C	2b	3	2	N	N
78217	Leeches, Medicinal	C	2b	3	U	N	N
78218	Lens, Camera, Surgical	A	1	1	1	N	N
78219	Light Based Over The Counter Wrinkle Reduction	B	2a	2	2	N	N
78220	Light Based Over-The-Counter Hair Removal	B	2a	2	2	N	N
78221	Light, Surgical, Accessories	A	1	1	2	N	N
78222	Light, Surgical, Carrier	A	1	1	2	N	N
78223	Light, Surgical, Ceiling Mounted	A	1	1	2	N	N
78224	Light, Surgical, Connector	A	1	1	2	N	N
78225	Light, Surgical, Endoscopic	A	1	1	2	N	N
78226	Light, Surgical, Fiberoptic	A	1	1	2	N	N
78227	Light, Surgical, Floor Standing	A	1	1	2	N	N
78228	Light, Surgical, Instrument	A	1	1	2	N	N
78229	Light, Ultraviolet, Dermatological	B	2a	2	2	N	N
78230	Loupe, Diagnostic/Surgical	A	1	1	1	N	N
78231	Low Energy Direct Current Thermal Ablation System	C	2b	3	2	N	N
78232	Maggots, Medical	B	2a	2	U	N	N
78233	Mallet	A	1	1	1	N	N
78234	Mallet, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78235	Marker, Ostia, Aorto-Saphenous Vein	B	2a	2	2	Y	N
78236	Marker, Radiographic, Implantable	C	2b	3	2	Y	N
78237	Marker, Skin	A	1	1	1	N	N
78238	Marker, Suture Identification	B	2a	2	U	N	N
78239	Mask, Surgical	A	1	1	2	N	N
78240	Massager, Vacuum, Light Induced Heating	B	2a	2	2	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78241	Material, External Aesthetic Restoration, No Adhesive	A	1	1	1	N	N
78242	Material, External Aesthetic Restoration, Used With Adhesive	A	1	1	1	N	N
78243	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction	C	2b	3	2	Y	N
78244	Mesh, Surgical	C	2b	3	2	Y	N
78245	Mesh, Surgical, Absorbable, Abdominal Hernia	C	2b	3	2	Y	N
78246	Mesh, Surgical, Absorbable, Fistula	C	2b	3	2	Y	N
78247	Mesh, Surgical, Absorbable, Large Abdominal Wall Defects	C	2b	3	2	Y	N
78248	Mesh, Surgical, Absorbable, Organ Support	C	2b	3	2	Y	N
78249	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon	C	2b	3	2	Y	N
78250	Mesh, Surgical, Absorbable, Plastic And Reconstructive Surgery	C	2b	3	2	Y	N
78251	Mesh, Surgical, Absorbable, Staple Line Reinforcement	C	2b	3	2	Y	N
78252	Mesh, Surgical, Absorbable, Thoracic, Chest Wall Reconstruction	C	2b	3	2	Y	N
78253	Mesh, Surgical, Acetabular, Hip, Prosthesis	C	2b	3	2	Y	N
78254	Mesh, Surgical, Collagen, Diaphragmatic Hernia	D	3	3	2	Y	N
78255	Mesh, Surgical, Collagen, Fistula	D	3	3	2	Y	N
78256	Mesh, Surgical, Collagen, Large Abdominal Wall Defects	D	3	3	2	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78257	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon	D	3	3	2	Y	N
78258	Mesh, Surgical, Collagen, Plastic And Reconstructive Surgery	D	3	3	2	Y	N
78259	Mesh, Surgical, Collagen, Plastics, Facial Implants	D	3	3	2	Y	N
78260	Mesh, Surgical, Collagen, Staple Line Reinforcement	D	3	3	2	Y	N
78261	Mesh, Surgical, Collagen, Thoracic, Chest Wall Reconstruction	D	3	3	2	Y	N
78262	Mesh, Surgical, Deployer	B	2a	2	2	N	N
78263	Mesh, Surgical, Deployment Balloon	C	2b	3	2	N	N
78264	Mesh, Surgical, For Stress Urinary Incontinence, Male	C	2b	3	2	Y	N
78265	Mesh, Surgical, Metal	C	2b	3	2	Y	N
78266	Mesh, Surgical, Non-Absorbable, Diaphragmatic Hernia	C	2b	3	2	Y	N
78267	Mesh, Surgical, Non-Absorbable, Facial Implants For Plastic Surgery	C	2b	3	2	Y	N
78268	Mesh, Surgical, Non-Absorbable, Large Abdominal Wall Defects	C	2b	3	2	Y	N
78269	Mesh, Surgical, Non-Absorbable, Orthopaedics, Reinforcement Of Tendon	C	2b	3	2	Y	N
78270	Mesh, Surgical, Non-Absorbable, Plastic And Reconstructive Surgery	C	2b	3	2	Y	N
78271	Mesh, Surgical, Non-Absorbable, Staple Line Reinforcement	C	2b	3	2	Y	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78272	Mesh, Surgical, Non-Absorbable, Thoracic, Chest Wall Reconstruction	C	2b	3	2	Y	N
78273	Mesh, Surgical, Non-Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed	C	2b	3	2	Y	N
78274	Mesh, Surgical, Non-Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed	C	2b	3	2	Y	N
78275	Mesh, Surgical, Non-Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator	C	2b	3	2	Y	N
78276	Mesh, Surgical, Polymeric	C	2b	3	2	Y	N
78277	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed	C	2b	3	2	Y	N
78278	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed	C	2b	3	2	Y	N
78279	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator	C	2b	3	2	Y	N
78280	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-Sling	C	2b	3	2	Y	N
78281	Microscope, Operating & Accessories, Ac-Powered, Ophthalmic	A	1	1	1	N	N
78282	Microscope, Operating, Non-Electric, Ophthalmic	A	1	1	1	N	N
78283	Microscope, Surgical	A	1	1	1	N	N
78284	Microscope, Surgical, General & Plastic Surgery	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78285	Mirror, General & Plastic Surgery	A	1	1	1	N	N
78286	Motor, Surgical Instrument, Ac-Powered	B	2a	2	1	N	N
78287	Motor, Surgical Instrument, Pneumatic Powered	B	2a	2	1	N	N
78288	N95 Respirator With Antimicrobial/Antiviral Agent	C	2b	3	2	N	N
78289	Needle, Aspiration And Injection, Disposable	B	2a	2	1	N	N
78290	Needle, Aspiration And Injection, Reusable	B	2a	2	1	N	N
78291	Needle, Aspiration And Needle, Reprocessed	B	2a	2	1	N	N
78292	Needle, Biopsy, Cardiovascular	B	2a	2	1	N	N
78293	Needle, Biopsy, Cardiovascular, Reprocessed	B	2a	2	1	N	N
78294	Needle, Catheter	B	2a	2	1	N	N
78295	Needle, Catheter, Reprocessed	B	2a	2	1	N	N
78296	Needle, Gastro-Urology	B	2a	2	1	N	N
78297	Needle, Gastro-Urology, Reprocessed	B	2a	2	1	N	N
78298	Needle, Suturing, Disposable	B	2a	2	1	N	N
78299	Needle, Suturing, Reusable	B	2a	2	1	N	N
78300	Needle, Tumor Localization	B	2a	2	1	N	N
78301	Negative Pressure Wound Therapy Non-Powered Suction Apparatus	B	2a	2	2	N	N
78302	Negative Pressure Wound Therapy Powered Suction Pump	B	2a	2	2	N	N
78303	Neurosurgical Laser With Mr Thermography	C	2b	3	2	N	N
78304	Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture For Chordae Tendinae Repair Or Replacement	B	2a	2	2	Y	Y
78305	Non-Surgical Isolation Gown	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78306	One-Way Air-Leak Valve	D	3	4	f	Y	N
78307	Orcel-Composite Cultured Skin	C	2b	3	f	Y	N
78308	Orthopedic Tray	A	1	1	1	N	N
78309	Osteotome	A	1	1	1	N	N
78310	Osteotome, Manual	A	1	1	1	N	N
78311	Over-The-Counter Powered Light Based Laser For Acne	A	1	1	2	N	N
78312	Pad, Eye	A	1	1	1	N	N
78313	Pad, Kelly	A	1	1	2	N	N
78314	Pediatric/Child Facemask	B	2a	2	2	N	N
78315	Percutaneous Surgical Set With Attachments	B	2a	2	2	N	N
78316	Pliers, Surgical	A	1	1	1	N	N
78317	Polymer, Composite Synthetic Ptfе With Carbon-Fiber, Ent	C	2b	3	2	Y	N
78318	Powder, Dusting, Surgical	C	2b	3	3	N	N
78319	Powdered Non-Natural Rubber Latex Surgeon'S Gloves	B	2a	2	1	N	N
78320	Powder-Free Non-Natural Rubber Latex Surgeon'S Gloves	B	2a	2	1	N	N
78321	Powered Laser Surgical Instrument	C	2b	3	2		
78322	Powered Laser Surgical Instrument With Microbeam\Fractional Output	C	2b	3	2	N	N
78323	Powered Light Based Non-Laser Surgical Instrument	B	2a	2	2	N	N
78324	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect	B	2a	2	2	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78325	Prosthesis, Adhesive, External	A	1	1	1	N	N
78326	Prosthesis, Breast, External, No Adhesive	A	1	1	1	N	N
78327	Prosthesis, Breast, External, Used With Adhesive	A	1	1	1	N	N
78328	Prosthesis, Breast, Inflatable, Internal, Saline	D	3	4	3	Y	N
78329	Prosthesis, Breast, Noninflatable, Internal, Silicone Gel-Filled	D	3	4	3	Y	N
78330	Prosthesis, Chin, Internal	C	2b	3	2	Y	N
78331	Prosthesis, Ear, Internal	C	2b	3	2	Y	N
78332	Prosthesis, Esophageal	C	2b	3	2	Y	N
78333	Prosthesis, Esophagus	C	2b	3	2	Y	N
78334	Prosthesis, Hip, Cement Restrictor	C	2b	3	2	Y	N
78335	Prosthesis, Nail	A	1	1	U	N	N
78336	Prosthesis, Nose, Internal	C	2b	3	2	Y	N
78337	Tube, Shunt, Endolymphatic	C	2b	3	2	Y	N
78338	Prosthesis, Ptfе/Carbon-Fiber	C	2b	3	2	Y	N
78339	Prosthesis, Tracheal, Expandable	C	2b	3	2	Y	N
78340	Prosthesis, Tracheal, Expandable, Polymeric	C	2b	3	2	Y	N
78341	Prosthesis, Tracheal, Preformed/Molded	C	2b	3	2	Y	N
78342	Pump, Portable, Aspiration (Manual Or Powered)	B	2a	2	2	N	N
78343	Pump, Vacuum, Electric, Suction-Type Electrode	C	2b	3	3	N	N
78344	Punch, Surgical	A	1	1	1	N	N
78345	Rasp	A	1	1	1	N	N
78346	Rasp, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78347	Razor, Surgical	A	1	1	1	N	N
78348	Respirator, Surgical	C	2b	3	2	N	N
78349	Retainer, Surgical	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78350	Retention Device, Suture	A	1	1	1	N	N
78351	Retractor	B	2a	2	1	N	N
78352	Ring (Wound Protector), Drape Retention, Internal	B	2a	2	2	N	N
78353	Saw	B	2a	2	1	N	N
78354	Saw, Electrically Powered	B	2a	2	1	N	N
78355	Saw, Manual And Accessories	A	1	1	1	N	N
78356	Saw, Pneumatically Powered	B	2a	2	1	N	N
78357	Saw, Powered, And Accessories	B	2a	2	1	N	N
78358	Scaffold, Partial Medial Meniscal Defects Extending Into The Red/White Zone, Resorbable Bovine Collagen	D	3	4	2	Y	N
78359	Scalpel, One-Piece	B	2a	2	1	N	N
78360	Scalpel, Ultrasonic, Reprocessed	C	2b	3	U	N	N
78361	Scissors, General, Surgical	A	1	1	1	N	N
78362	Scraper, Skin Specimen	A	1	1	U	N	N
78363	Sealant, Microbial	B	2a	2	2	N	N
78364	Sealant, Polymerizing	C	2b	3	3	Y	N
78365	Septal Stapler/Absorbable Staples	C	2b	3	2	Y	N
78366	Shave Prep Kit	A	1	1	2	N	N
78367	Shoe And Shoe Cover, Conductive	A	1	1	1	N	N
78368	Shoes, Operating-Room	A	1	1	1	N	N
78369	Silicone, Liquid, Injectable	C	2b	3	3	N	N
78370	Single Use Instrument Tray Kit	A	1	1	1	N	N
78371	Sizer, Mammary, Breast Implant Volume	B	2a	2	U	N	N
78372	Skin Prep Tray (Kit)	A	1	1	1	N	N
78373	Skin Resurfacing Rf Applicator	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78374	Snare, Surgical	A	1	1	1	N	N
78375	Solvent, Adhesive Tape	A	1	1	1	N	N
78376	Spatula, Orthopedic	A	1	1	1	N	N
78377	Spatula, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78378	Specula Accessories	A	1	1	1	N	N
78379	Speculum, Ent	A	1	1	1	N	N
78380	Speculum, Illuminated	A	1	1	1	N	N
78381	Speculum, Non-Illuminated	A	1	1	1	N	N
78382	Splint, Extremity, Inflatable, External	A	1	1	1	N	N
78383	Splint, Extremity, Non-Inflatable, External, Non-Sterile	A	1	1	1	N	N
78384	Splint, Extremity, Noninflatable, External, Sterile	A	1	1	1	N	N
78385	Staple, Implantable	C	2b	3	2	Y	N
78386	Staple, Implantable, Reprocessed	C	2b	3	2	N	N
78387	Staple, Removable (Skin)	B	2a	2	1	N	N
78388	Stapler, Surgical	B	2a	2	1	N	N
78389	Stent, Colonic, Metallic, Expandable	C	2b	3	2	Y	N
78390	Stent, Metallic, Expandable, Duodenal	C	2b	3	2	Y	N
78391	Stool, Operating-Room	A	1	1	1	N	N
78392	Strip, Adhesive, Closure, Skin	A	1	1	U	N	N
78393	Stripper, Vein, Disposable	A	1	1	1	N	N
78394	Stripper, Vein, Reusable	A	1	1	1	N	N
78395	Stylet, Surgical, General & Plastic Surgery	A	1	1	1	N	N
78396	Suit, Surgical	A	1	1	1	N	N
78397	Surgeon'S Gloves	B	2a	2	1	N	N
78398	Surgical Device, For Ablation Of Cardiac Tissue	D	3	4	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
878 GENERAL AND PLASTIC SURGERY DEVICES							
78399	Surgical Film	A	1	1	2	Y	Y
78400	Surgical Mask With Antimicrobial/Antiviral Agent	A	1	1	2	N	N
78401	Surgical Table Cushion	A	1	1	1	N	N
78402	Suture Kit	B	2a	2	2	N	N
78403	Suture Removal Kit	A	1	1	N	N	N
78404	Suture, Absorbable	C	2b	3	2	Y	N
78405	Suture, Absorbable, Natural	D	3	4	2	Y	N
78406	Suture, Absorbable, Synthetic	C	2b	3	2	Y	N
78407	Suture, Absorbable, Synthetic, Polyglycolic Acid	C	2b	3	2	Y	N
78408	Suture, Knot, Mechanical	C	2b	3	2	Y	N
78409	Suture, Nonabsorbable	C	2b	3	U	Y	N
78410	Suture, Nonabsorbable, Nitinol	B	2a	2	2	Y	N
78411	Suture, Nonabsorbable, Silk	C	2b	3	2	Y	N
78412	Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile	C	2b	3	2	Y	N
78413	Suture, Nonabsorbable, Synthetic, Polyamide	C	2b	3	2	Y	N
78414	Suture, Nonabsorbable, Synthetic, Polyester	C	2b	3	2	Y	N
78415	Suture, Nonabsorbable, Synthetic, Polyethylene	C	2b	3	2	Y	N
78416	Suture, Nonabsorbable, Synthetic, Polypropylene	C	2b	3	2	Y	N
78417	Suture, Recombinant Technology	C	2b	3	2	Y	N
78418	Suture, Surgical, Absorbable, Polydioxanone	C	2b	3	2	Y	N
78419	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene	C	2b	3	2	Y	N
78420	Suture, Surgical, Nonabsorbable, Poly (Vinylidene Fluoride)	C	2b	3	2	Y	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78421	System, Ablation, Microwave And Accessories	C	2b	3	2	N	N
78422	System, Ablation, Ultrasound And Accessories	B	2a	2	2	N	N
78423	System, Cryosurgical, Liquid Nitrogen, For Gastroenterology	C	2b	3	2	N	N
78424	System, Cryosurgical, Liquid Nitrogen, For Urology	C	2b	3	2	N	N
78425	System, Laser, Fiber Optic, Photodynamic Therapy	C	2b	3	3	N	N
78426	System, Laser, Photodynamic Therapy	C	2b	3	3	N	N
78427	System, Skin Closure	A	1	1	1	N	N
78428	System, Suction, Lipoplasty	C	2b	3	2	N	N
78429	System, Non-Coherent Light, Photodynamic Therapy	C	2b	3	3	N	N
78430	Table And Attachments, Operating-Room	A	1	1	1	N	N
78431	Table, Examination, Medical, Powered	A	1	1	1	N	N
78432	Table, Operating-Room, Ac-Powered	A	1	1	1	N	N
78433	Table, Operating-Room, Electrical	A	1	1	1	N	N
78434	Table, Operating-Room, Manual	A	1	1	1	N	N
78435	Table, Operating-Room, Mechanical	A	1	1	1	N	N
78436	Table, Operating-Room, Non-Electrical	A	1	1	1	N	N
78437	Table, Operating-Room, Pneumatic	A	1	1	1	N	N
78438	Table, Surgical With Orthopedic Accessories, Ac-Powered	A	1	1	1	N	N
78439	Table, Surgical With Orthopedic Accessories, Manual	A	1	1	1	N	N
78440	Tape, Camera, Surgical	A	1	1	1	N	N
78441	Tape, Measuring, Rulers And Calipers	A	1	1	1	N	N

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878 GENERAL AND PLASTIC SURGERY DEVICES							
78442	Tape, Orthopedic	A	1	1	1	N	N
78443	Tape, Surgical, Internal	C	2b	3	U	Y	N
78444	Tissue Adhesive For The Topical Approximation Of Skin	C	2b	3	2	N	N
78445	Tourniquet Kit	A	1	1	1	N	N
78446	Tourniquet, Gastro-Urology	A	1	1	1	N	N
78447	Tourniquet, Nonpneumatic	A	1	1	1	N	N
78448	Tourniquet, Pneumatic	B	2a	2	1	N	N
78449	Tray, Surgical	B	2a	2	1	N	N
78450	Tray, Surgical, Instrument	B	2a	2	1	N	N
78451	Trousers, Anti-Shock	B	2a	2	U	N	N
78452	Ultrasound, Skin Permeation	B	2a	2	2	N	N
78453	Unit, Airflow, Laminar	B	2a	2	2	N	N
78454	Unit, Cryosurgical, Accessories	C	2b	3	2	N	N
78455	Unit, Electrosurgical Andcoagulation, With Accessories	C	2b	3	2	N	N
78456	Unit, Isolation, Surgical	B	2a	2	2	N	N
78457	Vacuum Powered Body Fluid Collection Kit	B	2a	2	2	N	N
78459	Vise, Bench, Surgical	A	1	1	U	N	N
78460	Wax,Bone	C	2b	3	U	Y	N
78461	Wound Cleaner, Ultrasound	B	2a	2	2	N	N
78462	Wound Drain Catheter System	B	2a	2	2	N	N
78463	Wound Dressing With Poly(Diallyl Dimethyl Ammonium Chloride)(Pdadmac)	B	2a	2	2	N	N

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880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80001	Accessories, Pump, Infusion	B	2a	2	2	N	N
80002	Adminstration Set Docking Station	B	2a	2	2	N	N
80003	Antimicrobial Keyboard	B	2a	2	2	N	N
80004	Antimicrobial Medical Glove	B	2a	2	1	N	N
80005	Apparatus, Suction, Operating-Room, Wall Vacuum Powered	B	2a	2	2	N	N
80006	Applicator, Absorbent Tipped, Non-Sterile	A	1	1	1	N	N
80007	Applicator, Absorbent Tipped, Sterile	A	1	1	1	N	N
80008	Bag, Ice	A	1	1	1	N	N
80009	Bandage, Elastic	A	1	1	1	N	N
80010	Bandage, Liquid	B	2a	2	1	N	N
80011	Bandage, Liquid, Skin Protectant	B	2a	2	1	N	N
80011	Bandage, Liquid, Skin Protectant	B	2a	2	1	N	N
80012	Bariatric Bed	A	1	1	2	N	N
80013	Basin, Emesis	A	1	1	1	N	N
80014	Bassinet, Hospital	A	1	1	2	N	N
80015	Bed, Ac-Powered Adjustable Hospital	A	1	1	2	N	N
80016	Bed, Hydraulic, Adjustable Hospital	A	1	1	1	N	N
80017	Bed, Manual	A	1	1	1	N	N
80018	Bed, Pediatric Open Hospital	A	1	1	2	N	N
80019	Bed, Therapeutic, Ac-Powered, Adjustable Home-Use	A	1	1	2	N	N
80020	Bedding, Disposable, Medical	A	1	1	1	N	N
80021	Bedpan	A	1	1	1	N	N
80022	Binder, Abdominal	A	1	1	1	N	N
80023	Binder, Breast	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80024	Binder, Elastic	A	1	1	1	N	N
80025	Binder, Medical, Therapeutic	A	1	1	1	N	N
80026	Binder, Perineal	A	1	1	1	N	N
80027	Board, Bed	A	1	1	1	N	N
80028	Board, Cardiopulmonary	A	1	1	1	N	N
80029	Bone Marrow Collection/Transfusion Kit	B	2a	2	U	N	N
80030	Bottle, Collection And Trap, Breathing System (Uncalibrated)	A	1	1	2	N	N
80031	Bottle, Collection, Breathing System (Calibrated)	D	3	2	2	N	N
80032	Bottle, Collection, Vacuum	A	1	1	2	N	N
80033	Bottle, Hot/Cold Water	A	1	1	1	N	N
80034	Burn Kit With Drug	C	2b	3	U	N	N
80035	Burn Kit Without Drug	B	2a	2	U	N	N
80036	Cabinet, Ethylene-Oxide Gas Aerator	B	2a	2	2	N	N
80037	Catheter And Tip, Suction	B	2a	2	2	N	N
80038	Catheter, Percutaneous, Intraspinal, Short Term	C	2b	3	U	N	N
80040	Catheter, Umbilical Artery	B	2a	2	2	N	N
80041	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days	C	2b	3	2	Y	N
80042	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	B	2a	2	2	N	N
80043	Chair And Table, Medical	A	1	1	1	N	N
80044	Chair, Blood Donor	A	1	1	1	N	N
80045	Chair, Examination And Treatment	A	1	1	1	N	N
80046	Chair, Geriatric	A	1	1	1	N	N
80047	Chamber, Patient Isolation	B	2a	2	2	N	N

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880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80048	Chamber, Patient Transport Isolation	B	2a	2	2	N	N
80049	Chamber, Reverse Isolation, Patient Care	B	2a	2	2	N	N
80050	Check Valve, Retrograde Flow (In-Line)	B	2a	2	2	N	N
80051	Chest Drainage Kit	B	2a	2	2	N	N
80052	Cleaner, Air, Medical Recirculating	B	2a	2	2	N	N
80053	Cleaner, Ultrasonic, Medical Instrument	B	2a	2	1	N	N
80054	Cleaners, Medical Devices	B	2a	2	U	N	N
80055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	C	2b	3	2	N	N
80056	Container, Frozen Donor Tissue Storage	B	2a	2	U	N	N
80057	Container, I.V.	B	2a	2	2	N	N
80058	Container, Liquid Medication, Graduated	D	3	1	1	N	N
80059	Container, Sharps	B	2a	2	2	N	N
80060	Container, Supplementary Nitroglycerin	B	2a	2	U	N	N
80061	Controller, Closed-Loop Blood Glucose	D	3	4	3	N	N
80062	Controller, Infusion, Intravascular, Electronic	B	2a	2	U	N	N
80063	Counter, Sponge, Surgical	D	3	1	1	N	N
80064	Cover, Cast	A	1	1	1	N	N
80065	Cover, Mattress (Medical Purposes)	A	1	1	1	N	N
80066	Cream, Nasal, Topical, Mechanical Allergen Particle Barrier	B	2a	2	2	N	N
80067	Depressor, Tongue, Non-Surgical	A	1	1	1	N	N
80068	Detectors And Removers, Lice, (Including Combs)	A	1	1	1	N	N
80069	Device, Germicidal, Ultraviolet	B	2a	2	2	N	N
80070	Device, Intravascular Catheter Securement	A	1	1	1	N	N
80071	Device, Medical Examination, Ac Powered	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80072	Device, Needle Destruction	C	2b	3	3	N	N
80073	Device, Occlusion, Umbilical	A	1	1	1	N	N
80074	Device, Pasteurization, Hot Water	C	2b	3	2	N	N
80075	Device, Patient Transfer, Powered	A	1	1	2	N	N
80076	Device, Peritoneal Access, Subcutaneous, Implanted	C	2b	3	3	Y	N
80077	Device, Transfer, Patient, Manual	A	1	1	1	N	N
80078	Device, Vein Location, Liquid Crystal	A	1	1	1	N	N
80079	Device, Vein Stabilization	A	3	1	1	N	N
80080	Diabetes Take Home Kit	C	2b	3	U	N	N
80081	Disinfectant, Medical Devices	B	2a	2	1	N	N
80082	Disinfectant, Medical Devices	B	2a	2	2	N	N
80083	Dispenser, Liquid Medication	A	1	1	1	N	N
80084	Dressing, Compression	A	1	1	1	N	N
80085	Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic	D	3	2	U	N	N
80086	Dressing, Wound And Burn, Interactive	C	2b	3	3	N	N
80087	Dressing, Wound And Burn, Occlusive	B	2a	2	U	N	N
80088	Dressing, Wound, Collagen	D	3	2	U	N	N
80089	Dressing, Wound, Drug	D	3	2	U	N	N
80090	Dressing, Wound And Burn, Occlusive, Heated	B	2a	2	U	N	N
80091	Ear Irrigation Kit	B	2a	2	1	N	N
80092	Electrode, In Vivo Calcium Ion Selective	C	2b	3	U	N	N
80093	Fiber, Medical, Absorbent	A	1	1	1	N	N
80094	Filter, Infusion Line	B	2a	2	2	N	N
80095	Finger Cot	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80096	Gauze, External (With Drug/Biologic/Animal Source Material)	D	3	1	U	N	N
80097	Gauze/Sponge, Internal	C	2b	3	U	N	N
80098	Gauze/Sponge, Internal, With Drug/Biologic, Animal Source Material	D	3	4	U	N	N
80099	Glove, Patient Examination, Powder-Free	B	2a	2	2		zz
80100	Gown, Examination	A	1	1	1	N	N
80101	Heparin, Vascular Access Flush	C	2b	3	2	N	N
80102	Holder, Infant Position	A	3	1	1	N	N
80103	Implantable Radio Frequency Transponder System	C	2b	3	2	Y	N
80104	Implanted Subcutaneous Securement Catheter	C	2b	3	2	Y	N
80105	Incubator, Neonatal	C	2b	3	2	N	N
80106	Incubator, Neonatal Transport	C	2b	3	2	N	N
80107	Indicator, Biological Sterilization Process	B	2a	2	2	N	N
80108	Indicator, Biological, Liquid Chemical Sterilization Process	B	2a	2	2	N	N
80109	Indicator, Physical/Chemical Sterilization Process	B	2a	2	2	N	N
80110	Indicator, Physical/Chemical, Storage Temperature	B	2a	2	2	N	N
80111	Indicator, Sterilization	B	2a	2	2	N	N
80112	Indicator, Chemical, Enzymatic, Sterilization Process	B	2a	2	2	N	N
80113	Infant Positioner, Rx, Use In Highly Monitored Setting	A	1	1	1	N	N
80114	Infusor, Pressure, For I.V. Bags	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80115	Ingestible Event Marker	C	2b	3	2	N	N
80116	Injector, Fluid, Non-Electrically Powered	B	2a	2	2	N	N
80117	Injector, Pen	B	2a	2	2	N	N
80118	Insoles, Medical	A	1	1	1	N	N
80119	Intravenous Extension Tubing Set	B	2a	2	2	N	N
80120	Introducer, Syringe Needle	B	2a	2	2	N	N
80122	Kit, Chemical Snake-Bite	C	2b	3	3	N	N
80123	Kit, Decontamination	A	1	1	U	N	N
80124	Kit, Suction, Snake-Bite	B	2a	2	1	N	N
80125	Kit, Wound Dressing	B	2a	2	2	N	N
80126	Latex Patient Examination Glove	B	2a	2	1	N	N
80127	Lavage, Jet	B	2a	2	2	N	N
80128	Lift, Patient, Ac-Powered	B	2a	2	2	N	N
80129	Lift, Patient, Non-Ac-Powered	B	2a	2	1	N	N
80130	Light, Examination, Medical, Battery Powered	A	1	1	1	N	N
80131	Liquid Chemical Processing System	B	2a	2	2	N	N
80132	Locator, Acupuncture Point	B	2a	2	2	N	N
80133	Lubricant, Patient	B	2a	2	1	N	N
80134	Lubricant, Vaginal, Patient	B	2a	2	1	N	N
80135	Manometer, Spinal-Fluid	B	2a	2	2	N	N
80136	Mattress, Air Flotation, Alternating Pressure	B	2a	2	2	N	N
80137	Mattress, Flotation Therapy, Non-Powered	A	1	1	1	N	N
80138	Mattress, Water, Temperature Regulated	B	2a	2	1	N	N
80140	Medical Computers And Software For Ophthalmic Use	B	2a	2	3	N	N
80141	Medical Device Data System	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80142	Medical Gloves With Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs	B	2a	2	1	N	N
80144	Medication Management System, Remote	D	3	2	2	N	N
80145	Meter, Jaundice	B	2a	2	3	N	N
80146	Microfilter, Blood Transfusion	B	2a	2	2	N	N
80147	Monitor, Bed Patient	A	1	1	1	N	N
80148	Monitor, Electric For Gravity Flow Infusion Systems	B	2a	2	2	N	N
80149	Monitor, Skin Resistance/Skin Temperature, For Insulin Reactions	C	2b	3	3	N	N
80150	Monitor, Spinal-Fluid Pressure, Electrically Powered	C	2b	3	2	N	N
80151	N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies	B	2a	2	2	N	N
80152	Needle, Acupuncture, Single Use	B	2a	2	2	N	N
80153	Needle, Hypodermic, Single Lumen	B	2a	2	2	N	N
80154	Needle, Hypodermic, Single Lumen, Reprocessed	B	2a	2	2	N	N
80155	Nipple, Lambs Feeding	B	2a	2	1	N	N
80156	Nursing Pad, Cohesive Gel	B	2a	2	1	N	N
80157	Nursing Pad, Hydrogel	B	2a	2	1	N	N
80158	Nursing Pad, Polyurethane Pad With Starch Copolymer, Glycerin, And Surfactant (F-68)	B	2a	2	1	N	N
80159	Oral Lubricant	A	1	1	1	N	N
80160	Pad, Alcohol, Device Disinfectant	A	1	1	U	N	N
80161	Pad, Neonatal Eye	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80162	Patient Bed With Canopy/Restraints	A	1	1	1	N	N
80163	Patient Examination Glove	B	2a	2	1	N	N
80164	Patient Examination Glove, Specialty	B	2a	2	1	N	N
80165	Percutaneous, Implanted, Long-Term Intravascular Catheter Accessory For Catheter Position	C	2b	3	2	Y	N
80166	Peripheral Catheter Insertion Kit	B	2a	2	2	N	N
80167	Pill Crusher/Cutter	A	1	1	1	N	N
80168	Polymer Patient Examination Glove	B	2a	2	1	N	N
80169	Port & Catheter, Implanted, Subcutaneous, Intraperitoneal	C	2b	3	U	Y	N
80170	Port & Catheter, Implanted, Subcutaneous, Intravascular	C	2b	3	2	Y	N
80171	Port & Catheter, Implanted, Subcutaneous, Intraventricular	C	2b	3	U	Y	N
80172	Port Introducer Kit	B	3	2	2	N	N
80173	Port, Intraosseous, Implanted	C	3	3	2	Y	N
80174	Port, Protector/Cushion	B	3	2	2	N	N
80175	Powdered Latex Patient Examination Glove	B	3	2	1	N	N
80176	Powdered Nitrile Patient Examination Glove	B	3	2	1	N	N
80177	Powdered Polychloroprene Patient Examination Glove	B	3	2	1	N	N
80178	Powdered Vinyl Patient Examination Glove	B	3	2	1	N	N
80179	Powder-Free Guayle Rubber Examination Glove	B	3	2	1	N	N
80180	Powder-Free Polychloroprene Patient Examination Glove	B	3	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80181	Protector, Skin Pressure	A	3	1	1	N	N
80182	Protector, Wound, Plastic	A	1	1	U	N	N
80183	Pump, Drug Administration, Closed Loop	D	3	4	3	N	N
80184	Pump, Infusion	C	3	3	2	N	N
80185	Pump, Infusion, Analytical Sampling	C	3	3	2	N	N
80186	Pump, Infusion, Elastomeric	B	3	2	2	N	N
80187	Pump, Infusion, Enteral	B	3	2	2	N	N
80188	Pump, Infusion, Gallstone Dissolution	C	3	3	2		N
80189	Pump, Infusion, Implanted, Programmable	C	3	3	3	Y	N
80190	Pump, Infusion, Insulin	D	3	3	2	N	N
80191	Pump, Infusion, Insulin Bolus	C	3	3	2	N	N
80192	Pump, Infusion, Ophthalmic	C	3	3	2	N	N
80193	Pump, Infusion, Pca	C	3	3	2	N	N
80194	Purifier, Air, Ultraviolet, Medical	B	3	2	2	N	N
80195	Purifier, Water, Ultraviolet, Medical	C	3	3	2	N	N
80196	Radiant Infant Warmer Cabinet	C	3	3	2	N	N
80197	Radiation Attenuating Medical Glove	B	2a	2	1	N	N
80198	Regulator, Vacuum	B	2a	2	2	N	N
80199	Respirator, N95, For Use By The General Public In Public Health Medical Emergencies	B	2a	2	2	N	N
80200	Restraint, Patient, Conductive	B	2a	2	1	N	N
80201	Restraint, Protective	A	3	1	1	N	N
80202	Ring Cutter	A	1	1	1	N	N
80203	Saline, Vascular Access Flush	C	2b	3	2	N	N
80204	Scale, Patient	A	1	1	1	N	N
80205	Scale, Sponge, Surgical, Electrically-Powered	B	2a	2	1	N	N

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880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80206	Scale, Stand-On, Patient	A	1	1	1	N	N
80207	Scale, Surgical Sponge	A	1	1	1	N	N
80208	Scissors, Medical, Disposable	A	1	1	1	N	N
80209	Set, Administration, Intravascular	B	2a	2	2	N	N
80210	Set, Blood Transfusion	B	2a	2	2	N	N
80211	Set, I.V. Fluid Transfer	B	2a	2	2	N	N
80212	Set, Oral Administration	B	2a	2	U	N	N
80213	Sheet, Burn	A	1	1	1	N	N
80214	Shield, Nipple	A	1	1	1	N	N
80215	Software, Transmission And Storage, Patient Data	B	2a	2	N	N	N
80216	Solution, Cold Sterilizing	B	2a	2	2	N	N
80217	Stand, Infusion	A	1	1	1	N	N
80218	Sterilant, Medical Devices	B	2a	2	2	N	N
80219	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories	B	2a	2	2	N	N
80220	Sterilizer, Chemical	B	2a	2	2	N	N
80221	Sterilizer, Dry Heat	B	2a	2	2	N	N
80222	Sterilizer, Ethylene-Oxide Gas	B	2a	2	2	N	N
80223	Sterilizer, Steam	B	2a	2	2	N	N
80225	Stimulator, Intramuscular, Automatic	C	2b	3	2	N	N
80226	Stocking, Medical Support (For General Medical Purposes)	A	1	1	1	N	N
80227	Stocking, Medical Support (To Prevent Pooling Of Blood In Legs)	A	1	1	2	N	N
80228	Stopcock, I.V. Set	B	2a	2	2	N	N
80229	Stretcher, Hand-Carried	A	1	1	1	N	N

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880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80230	Stretcher, Patient Restraint	A	1	1	1	N	N
80231	Stretcher, Wheeled	A	1	1	2	N	N
80232	Strip, Temperature, Forehead, Liquid Crystal	A	1	1	2	N	N
80233	Support, Scrotal, Therapeutic	A	1	1	1	N	N
80234	Syringe, Antistick	B	2a	2	2	N	N
80235	Syringe, Irrigating (Non Dental)	B	2a	2	1	N	N
80236	Syringe, Piston	B	2a	2	2	N	N
80237	Syringe, Piston, Reprocessed	B	2a	2	2	N	N
80238	System, Delivery, Allergen And Vaccine	B	2a	2	U	N	N
80239	System/Device, Pharmacy Compounding	B	2a	2	2	N	N
80240	Tape And Bandage, Adhesive	A	1	1	1	N	N
80241	Tape And Bandage, Adhesive (With Disinfectant)	A	1	1	U	N	N
80242	Thermometer, Clinical Color Change	B	2a	2	1	N	N
80243	Thermometer, Clinical Mercury	A	1	1	2	N	N
80244	Thermometer, Electronic, Clinical	B	2a	2	2	N	N
80245	Thermometer, Exhaled Breath	B	2a	2	2	N	N
80246	Timer, Apgar	A	1	1	1	N	N
80247	Topical Approximation System	A	1	1	1	N	N
80248	Trap, Sterile Specimen	B	2a	2	2	N	N
80249	Tube, Aspirating, Flexible, Connecting	B	2a	2	2	N	N
80250	Tubing, Fluid Delivery	B	2a	2	2	N	N
80251	Tubing, Noninvasive	A	1	1	2	N	N
80252	Tunneled Catheter Remover	B	2a	2	2	N	N
80253	Unit, Neonatal Phototherapy	C	2b	3	2	N	N
80254	Urinal	A	1	1	1	N	N
80255	Vinyl Patient Examination Glove	B	2a	2	1	N	N

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880 GENERAL HOSPITAL AND PERSONAL USE DEVICES							
80256	Warmer, Infant Radiant	C	2b	3	2	N	N
80257	Warmer, Irrigation Solution	B	2a	2	U	N	N
80258	Warmer, Microwave, Infusion Fluid	D	2b	3	U	N	N
80259	Warmer, Thermal, Infusion Fluid	D	2a	2	U	N	N
80260	Washer Of Body Waste Receptacles	D	1	1	1	N	N
80261	Water, Vascular Access Flush	D	2b	3	2	N	N
80262	Wrap, Sterilization	D	2a	2	2	N	N

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882 NEUROLOGICAL DEVICES							
82001	Accessory,Barium Sulfate,Methyl Methacrylate For Cranioplasty	C	2b	3	2	Y	N
82002	Adhesive, Tissue For Aneurysmorrhaphy	D	3	4	3	Y	N
82003	Amplifier, Physiological Signal	B	2a	2	2	N	N
82004	Amplitude-Integrated Electroencephalograph	B	2a	2	2	N	N
82005	Analyzer, Rigidity	B	2a	2	2	N	N
82006	Analyzer, Spectrum, Electroencephalogram Signal	A	1	1	1	N	N
82007	Anvil, Skull Plate	A	1	1	1	N	N
82008	Applier, Aneurysm Clip	B	2a	2	2	N	N
82009	Ataxiagraph	A	1	1	1	N	N
82010	Automatic Event Detection Software For Full-Montage Electroencephalograph	B	2a	2	2	N	N
82011	Automatic Event Detection Software For Polysomnograph With Electroencephalograph	B	2a	2	2	N	N
82012	Balloon,Detachable,For Neurovascular Occlusion	C	2b	3	2	Y	Y
82013	Block, Bite	A	1	1	2	N	N
82014	Block, Test, Ultrasonic Scanner Calibration	A	1	1	1	N	N
82015	Burst Suppression Detection Software For Electroencephalograph	B	2a	2	2	N	N
82016	Cannula, Ventricular	B	2a	2	1	N	N
82017	Catheter, Intravascular Occluding	D	3	4	3	N	N
82018	Catheter, Neuro-Vasculature, Occluding Ballon	D	3	4	3	N	Y
82019	Catheter, Neuro-Vasculature, Occluding Balloon	B	2a	2	U	N	N
82020	Catheter, Ventricular	D	3	4	2	N	N

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882 NEUROLOGICAL DEVICES							
82021	Catheter, Ventricular (Containing Antibiotic Or Antimicrobial Agents)	D	3	4	2	Y	N
82022	Chair, Neurosurgical	A	1	1	1	N	N
82023	Clamp, Carotid Artery	B	2a	2	2	Y	N
82024	Clip, Aneurysm	D	3	4	2	Y	N
82025	Clip, Implanted Malleable	D	3	4	2	Y	N
82026	Clip, Scalp	B	2a	2	2	N	N
82027	Computer Assisted Hair Harvesting System	C	2b	3	2	N	N
82028	Conditioner, Signal, Physiological	B	2a	2	2	N	N
82029	Cover, Burr Hole	C	2b	3	2	Y	N
82030	Cranial Distraction System	C	2b	3	2	Y	Y
82031	Cuff, Nerve	C	2b	3	2	Y	N
82032	Deep Brain Stimulator For Obsessive Compulsive Disorder (Ocd)	D	3	3	U	Y	N
82033	Device, Acupressure	A	1	1	U	N	N
82034	Device, Aversive Conditioning	B	2a	2	2	N	N
82035	Device, Biofeedback	B	2a	2	2	N	N
82036	Device, Discharge, Electrostatic (For Pain Relief)	B	2a	2	U	N	N
82037	Device, Electroconvulsive Therapy	C	2b	3	3	N	N
82038	Device, Galvanic Skin Response Measurement	B	2a	2	2	N	N
82039	Device, Monitoring, Intracranial Pressure	D	3	4	2	N	N
82040	Device, Nerve Conduction Velocity Measurement	B	2a	2	2	N	N
82041	Device, Neurosurgical Fragmentation And Aspiration	D	3	4	U	N	N
82042	Device, Neurovascular Embolization	D	3	4	2	Y	N
82043	Device, Skin Potential Measurement	B	2a	2	2	N	N

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882 NEUROLOGICAL DEVICES							
82044	Device, Sleep Assessment	U	U	U	U	N	N
82045	Device, Surgical, Cryogenic	C	2b	3	2	N	N
82046	Device, Temperature Measurement, Direct Contact, Powered	B	2a	2	2	N	N
82047	Device, Vibration Threshold Measurement	U	U	U	U	N	N
82048	Device, Cpr Assist	A	1	1	U	N	N
82049	Diaphragmatic/Phrenic Nerve Laparoscopically-Implanted Stimulator	D	3	4	f	Y	Y
82050	Discriminator, Two-Point	A	1	1	1	N	N
82051	Drills, Burrs, Trephines & Accessories (Compound, Powered)	B	2a	2	2	N	N
82052	Drills, Burrs, Trephines & Accessories (Manual)	B	2a	2	2	N	N
82053	Drills, Burrs, Trephines & Accessories (Simple, Powered)	B	2a	2	2	N	N
82054	Drills, Burrs, Trephines And Accessories (Manual), Reprocessed	B	2a	2	2	N	N
82055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	2	N	N
82056	Drills, Burrs, Trephines, And Accessories (Powered Compound), Reprocessed	B	2a	2	2	N	N
82057	Dura Substitute	D	3	4	2	Y	N
82058	Eating Disorder Conditioning Tool	D	3	2	2	N	N
82059	Echoencephalograph	B	2a	2	2	N	N
82060	Electrode, Cortical	B	2a	2	2	N	N
82061	Electrode, Cutaneous	B	2a	2	2	N	N
82062	Electrode, Depth	D	3	4	2	N	N

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882 NEUROLOGICAL DEVICES							
82063	Electrode, Nasopharyngeal	D	3	2	2	N	N
82064	Electrode, Needle	B	2a	2	2	N	N
82065	Electrode, Spinal Epidural	D	3	4	2	Y	N
82066	Electrode, Stabilized Epidural Spinal	D	3	4	3	Y	N
82067	Electronic Media, Nausea	B	2a	2	U	N	N
82068	Encephalogram Telemetry System	C	2b	3	2	N	N
82069	Endoscope, Neurological	B	2a	2	2	N	N
82070	Esthesiometer	A	1	1	1	N	N
82071	Evoked Potential Stimulator, Thermal	B	2a	2	2	N	N
82072	Fastener, Plate, Cranioplasty	C	2b	3	2	Y	N
82073	Fork, Tuning	A	1	1	1	N	N
82074	Full-Montage Standard Electroencephalograph	B	2a	2	2	N	N
82075	Generator, Electroencephalograph Test Signal	A	1	1	1	N	N
82076	Generator, Lesion, Radiofrequency	C	2b	3	2	N	N
82077	Handpiece (Brace), Drill	A	1	1	1	N	N
82078	Headframe	B	2a	2	U	N	N
82079	Headrest, Neurosurgical	A	3	1	1	N	N
82080	Holder, Head, Neurosurgical (Skull Clamp)	A	1	1	2	N	N
82081	Human Lyophilized Dura Mater	D	3	4	2	Y	N
82082	Implanted Cerebellar Stimulator	D	3	4	3	Y	N
82083	Implanted Diaphragmatic/Phrenic Nerve Stimulator	D	3	4	3	Y	N
82084	Implanted Subcortical Electrical Stimulator (Motor Disorders)	D	3	4	U	Y	N
82085	Index-Generating Electroencephalograph Software	D	3	2	2	N	N

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882 NEUROLOGICAL DEVICES							
82086	Infrared Hematoma Detector	C	2b	3	2	N	N
82087	Instrument, Clip Forming/Cutting	A	1	1	1	N	N
82088	Instrument, Clip Removal	D	3	1	1	N	N
82089	Instrument, Clip, Forming/Cutting, Reprocessed	D	3	1	1	N	N
82090	Instrument, Cranioplasty Material Forming	A	1	1	1	N	N
82091	Instrument, Dowel Cutting	A	1	1	2	N	N
82092	Instrument, Microsurgical	A	1	1	1	N	N
82093	Instrument, Shunt System Implantation	B	2a	2	1	N	N
82094	Instrument, Surgical, Non-Powered	A	1	1	1	N	N
82095	Interferential Current Therapy	B	2a	2	U	N	N
82096	Intracranial Aneurysm Flow Diverter	D	3	4	3	Y	N
82097	Intracranial Neurovascular Stent	D	3	4	f	Y	N
82098	Intraoperative Orthopedic Joint Assessment Aid	B	2a	2	2	N	N
82099	Laser, Neurosurgical	C	2b	3	3	N	N
82100	Laser, Neurosurgical, Argon	C	2b	3	3	N	N
82101	Leukotome	A	1	1	1	N	N
82102	Magnetoencephalograph	B	3	2	2	N	N
82103	Magnetotherapy Device For Pain Relief	B	2a	2	2	N	N
82104	Media, Electroconductive	B	2a	2	2	N	N
82105	Methyl Methacrylate For Aneurysmorrhaphy	C	2b	3	2	Y	N
82106	Methyl Methacrylate For Cranioplasty	C	2b	3	2	Y	N
82107	Monitor, Alpha	C	2b	3	2	N	N
82108	Monitor, Blood-Flow, Cerebral, Thermal Diffusion	D	3	4	3	N	N
82109	Monitor, Intracranial Pressure, Implanted	D	3	4	3	Y	N
82110	Monitor, Lesion Temperature	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
882 NEUROLOGICAL DEVICES							
82111	Motor, Drill, Electric	B	2a	2	2	N	N
82112	Motor, Drill, Pneumatic	B	2a	2	2	N	N
82113	Needle, Neurosurgical Suture	B	2a	2	1	N	N
82114	Neurological Stereotaxic Instrument	B	2a	2	2	N	N
82115	Neurological Stereotaxic Instrument, Real-Time Intraoperative Mri	B	2a	2	2	N	N
82116	Neurological Tray	B	2a	2	1	N	N
82117	Neurosurgical Paddie	B	2a	2	2	N	N
82118	Non-Normalizing Quantitative Electroencephalograph Software	B	2a	2	2	N	N
82119	Normalizing Quantitative Electroencephalograph Software	B	2a	2	2	N	N
82120	Nystagmograph	B	2a	2	2	N	N
82121	Orthopedic Computer Controlled Surgical System	B	2a	2	2	N	N
82122	Orthopedic Stereotaxic Instrument	B	2a	2	2	N	N
82123	Orthosis, Cranial	B	2a	2	2	N	N
82124	Orthosis, Cranial, Laser Scan	C	2b	3	2	N	N
82125	Patient Specific Manual Navigation System	B	2a	2	2	N	N
82126	Patient Specific Manual Orthopedic Stereotaxic System	B	2a	2	2	N	N
82127	Percussor	A	1	1	1	N	N
82128	Pinwheel	A	1	1	1	N	N
82129	Plate, Cranioplasty, Preformed, Alterable	C	2b	3	2	Y	N
82130	Plate, Cranioplasty, Preformed, Non-Alterable	C	2b	3	2	Y	N
82131	Plethysmograph, Ocular	C	2b	3	3	N	N
82132	Polymeric Neurovascular Embolization	D	3	4	f	Y	N

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882 NEUROLOGICAL DEVICES							
82133	Probe, Radiofrequency Lesion	B	2a	2	2	N	N
82134	Punch, Skull	A	1	1	1	N	N
82135	Rack, Clip	A	1	1	1	N	N
82136	Recorder, Attention Task Performance	U	U	U	U	N	N
82137	Reduced- Montage Standard Electroencephalograph	B	2a	2	2	N	N
82138	Transcranial Magnetic Stimulator	C	2b	3	2	N	N
82139	Retractor, Self-Retaining, For Neurosurgery	A	1	1	2	N	N
82140	Rheoencephalograph	D	3	4	3	N	N
82141	Rongeur, Manual	D	3	1	2	N	N
82142	Rongeur, Powered	B	2a	2	2	N	N
82143	Screwdriver, Skullplate	A	1	1	1	N	N
82144	Sealant, Dural	D	3	4	3	Y	Y
82145	Shunt, Central Nervous System And Components	D	3	4	2	Y	N
82146	Source Localization Software For Electroencephalograph Or Magnetoencephalograph	B	2a	2	2	N	N
82147	Standard Polysomnograph With Electroencephalograph	B	2a	2	2	N	N
82148	Stimulator, Auditory, Evoked Response	B	2a	2	2	N	N
82149	Stimulator, Autonomic Nerve, Implanted (Depression)	D	3	4	3	Y	N
82150	Stimulator, Autonomic Nerve, Implanted For Epilepsy	D	3	4	3	Y	N
82151	Stimulator, Brain, Implanted, For Behavior Modification	D	3	4	U	Y	N

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882 NEUROLOGICAL DEVICES							
82152	Stimulator, Cranial Electrotherapy	C	2b	3	3	N	N
82153	Stimulator, Electrical, Evoked Response	B	2a	2	2	N	N
82154	Stimulator, Electrical, Implanted, For Parkinsonian Symptoms	D	3	4	3	Y	N
82155	Stimulator, Electrical, Implanted, For Parkinsonian Tremor	D	3	4	3	Y	N
82156	Stimulator, Electrical, Transcutaneous, For Arthritis	B	2a	2	2	N	N
82157	Stimulator, Electrical, Transcutaneous, For Diabetic Retinopathy	C	2b	3	N	N	N
82158	Stimulator, Electrical, Transcutaneous, With Limited Output, For Aesthetic Purposes	B	2a	2	2	N	N
82159	Stimulator, Electro-Acupuncture	B	2a	2	U	N	N
82160	Stimulator, Functional Walking Neuromuscular, Non-Invasive	C	2b	3	3	N	N
82161	Stimulator, Intracerebral/Subcortical, Implanted	D	3	4	3	Y	N
82162	Stimulator, Low Electric Field, Tumor Treatment	B	2a	2	3	N	Y
82163	Stimulator, Mechanical, Evoked Response	B	2a	2	2	N	N
82164	Stimulator, Nerve, Electrical, Percutaneous (Pens), For Pain Relief	B	2a	2	2	N	N
82165	Stimulator, Nerve, Electrical, Transcutaneous, Limited Output, Arthritis Pain Relief	B	2a	2	2	N	N
82166	Stimulator, Nerve, Electrical, Transcutaneous, With Limited Output, For Pain Relief	B	2a	2	2	N	N
82167	Stimulator, Nerve, Transcutaneous, For Pain Relief	B	2a	2	2	N	N

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882 NEUROLOGICAL DEVICES							
82168	Stimulator, Nerve, Transcutaneous, Over-The-Counter	B	2a	2	2	N	N
82169	Stimulator, Neuromuscular, External Functional	B	3	2	2	N	N
82170	Stimulator, Neuromuscular, Implanted	D	3	4	3	Y	N
82171	Stimulator, Peripheral Nerve, Implanted (Pain Relief)	C	3	3	2	Y	N
82172	Stimulator, Photic, Evoked Response	B	3	2	2	N	N
82173	Stimulator, Spinal-Cord, Implanted (Pain Relief)	D	3	4	2	Y	N
82174	Stimulator, Spinal-Cord, Implanted For Peripheral Vascular Disease	D	3	4	3	Y	N
82175	Stimulator, Spinal-Cord, Implanted, For Bladder Evacuation	D	3	4	3	Y	N
82176	Stimulator, Spinal-Cord, Totally Implanted For Pain Relief	D	3	4	3	Y	N
82177	Stimulator, Subcortical, Implanted For Epilepsy	D	3	4	3	Y	N
82178	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	C	3	3	2	N	N
82179	Stimulator, Transdermal	C	2b	3	3	N	N
82180	Stimulator, Vestibular Acceleration, Therapeutic	C	3	3	3	N	N
82181	Strip, Craniosynostosis, Preformed	C	3	3	2	Y	N
82182	Surgical Kit	D	3	4	f	N	N
82183	Test, Temperature Discrimination	U	3	U	U	N	N
82184	Tester, Electrode/Lead, Electroencephalograph	B	3	2	1	N	N
82185	Tissue Adhesive For Use In Embolization Of Brain Arteriovenous Malformations	D	3	4	3	N	N
82186	Tong, Skull For Traction	B	3	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
882 NEUROLOGICAL DEVICES							
82187	Tracking, Soft Tissue, Intraoperative	D	3	3	2	N	Y
82188	Transducer, Tremor	B	3	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84001	Accessory, Assisted Reproduction	B	2a	2	2	N	N
84002	Amnioscope, Transabdominal (Fetoscope) (And Accessories)	D	3	4	U	N	N
84003	Amniotome	B	2a	2	1	N	N
84004	Analyzer, Data, Obstetric	C	2b	3	3	N	N
84005	Applicator, Vaginal	A	1	1	1	N	N
84006	Aspirator, Endocervical	B	2a	2	2	N	N
84007	Aspirator, Endometrial	B	2a	2	2	N	N
84008	Aspirator, Ultrasonic	B	2a	2	3	N	N
84009	Band, Tubal Occlusion	C	2b	3	3	Y	N
84010	Barrier, Absorbable, Adhesion	C	2b	3	3	N	N
84011	Barrier,Std,Oral Sex	C	2b	3	2	N	N
84012	Bell, Circumcision	A	1	1	2	N	N
84013	Breast Pump Kit	B	2a	2	2	N	N
84014	Brush, Endometrial	B	2a	2	2	N	N
84015	Caliper, Fetal Head, Ultrasonic	C	2b	3	2	N	N
84016	Cannula, Intrauterine Insemination	B	2a	2	2	N	N
84017	Cannula, Manipulator/Injector, Uterine	B	2a	2	U	N	N
84018	Cannula, Suction, Uterine	B	2a	2	2	N	N
84019	Cap, Cervical	B	2a	2	2	N	N
84020	Cap, Cervical, Contraceptive	C	2b	3	3	N	N
84021	Catheter, Assisted Reproduction	B	2a	2	2	N	N
84022	Catheter, Balloon, Transcervical	B	2a	2	3	N	N
84023	Catheter, Intrauterine And Introducer	B	2a	2	2	N	N
84024	Catheter, Sampling, Chorionic Villus	B	2a	2	3	N	N
84025	Catheters, Salpingography	B	2a	2	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84026	Cesarean Section Kit	B	2a	2	2	N	N
84027	Chamber, Decompression, Abdominal	C	2b	3	3	N	N
84028	Circumcision Tray	B	2a	2	2	N	N
84029	Clamp And Cutter, Umbilical	A	1	1	2	N	N
84030	Clamp, Circumcision	A	1	1	2	N	N
84031	Clamp, Umbilical	A	1	1	2	N	N
84032	Clamp, Uterine	D	3	1	1	N	N
84033	Cleidoclast	A	1	1	2	N	N
84034	Clip, Drape, Lithotomy	B	2a	2	2	N	N
84035	Clip, Tubal Occlusion	C	2b	3	3	Y	N
84036	Coagulator, Culdoscopic (And Accessories)	B	2a	2	2	N	N
84037	Coagulator, Hysteroscopic (And Accessories)	B	2a	2	2	N	N
84038	Coagulator, Laparoscopic, Unipolar (And Accessories)	B	2a	2	2	N	N
84039	Coagulator-Cutter, Endoscopic, Bipolar (And Accessories)	B	2a	2	2	N	N
84040	Coagulator-Cutter, Endoscopic, Unipolar (And Accessories)	B	2a	2	2	N	N
84041	Colposcope (And Colpomicroscope)	B	2a	2	2	N	N
84042	Condom	?	?	2, 3, 4	2	N	N
84043	Condom With Nonoxynol-9	B	2a	2	2	N	N
84044	Condom, Female, Animal Tissue	C	2b	3	3	N	N
84045	Condom, Female, Single-Use	C	2b	3	3	N	N
84046	Condom, Synthetic	C	2b	3	2	N	N
84047	Contraception Calculator	B	2a	2	U	N	N
84048	Controller, Abortion Unit, Vacuum	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84049	Cranioclast	A	1	1	2	N	N
84050	Craniotribe	A	1	1	2	N	N
84051	Culdocentesis Kit	B	2a	2	2	N	N
84052	Culdoscope (And Accessories)	B	2a	2	2	N	N
84053	Cup, Menstrual	B	2a	2	2	N	N
84054	Curette, Suction, Endometrial (And Accessories)	B	2a	2	2	N	N
84055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	1	N	N
84056	Cytology Kit	B	2a	2	2	N	N
84057	Device, Engorgement, Clitoral	B	2a	2	2	N	N
84058	Device, Fertility Diagnostic, Proceptive	D	3	2	U	N	N
84059	Device, Intrauterine, Contraceptive And Introducer	C	2b	3	3	Y	N
84060	Device, Occlusion, Tubal, Contraceptive	C	2b	3	3	Y	N
84061	Device, Semen Analysis	B	2a	2	U	N	N
84062	Device, Thermal Ablation, Endometrial	C	2b	3	3	N	N
84063	Diaphragm, Contraceptive (And Accessories)	D	3	2	2	N	N
84064	Dilator, Cervical, Expandable	C	2b	3	3	N	N
84065	Dilator, Cervical, Fixed Size	B	2a	2	1	N	N
84066	Dilator, Cervical, Hygroscopic-Laminaria	B	2a	2	2	N	N
84068	Dilator, Cervical, Vibratory	C	2b	3	3	N	N
84069	Dilator, Vaginal	B	2a	2	2	N	N
84070	Doppler, Fetal, Ultrasound	C	2b	3	2	N	N
84071	Douche Apparatus, Vaginal, Therapeutic	B	2a	2	1	N	N
84072	Drain, Cervical	B	2a	2	2	N	N
84073	Ductoscope, Breast	B	2a	2	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84074	Electrocautery, Endoscopic And Accessories	C	2b	3	2	N	N
84075	Electrocautery, Gynecologic (And Accessories)	C	2b	3	2	N	N
84076	Electrode, Circular (Spiral), Scalp And Applicator	B	2a	2	2	N	N
84077	Electrode, Clip, Fetal Scalp (And Applicator)	B	2a	2	3	N	N
84078	Elevator, Uterine	A	1	1	2	N	N
84079	Emergency Obstetrical Kit	B	2a	2	1	N	N
84080	Endometrial Sampling Kit	B	3	2	2	N	N
84081	Endoscope, Fetal Blood Sampling (And Accessories)	D	3	4	2	N	N
84082	Endoscope, Transcervical (Amnioscope)(And Accessories)	B	2a	2	2	N	N
84083	Extractor, Vacuum, Fetal	B	2a	2	2	N	N
84084	Falloposcope	B	2a	2	U	N	N
84085	Fluid, Cytological Collection	B	2a	2	3	N	N
84086	Fluid, Hysteroscopy	D	3	2	3	N	N
84087	Forceps, Biopsy, Gynecological	B	2a	2	1	N	N
84088	Forceps, Biopsy, Gynecological, Reprocessed	B	2a	2	2	N	N
84089	Forceps, Obstetrical	D	3	1	2	N	N
84090	Forceps, Surgical, Gynecological	D	3	1	2	N	N
84091	Forensic Evidence Sexual Assault Kit	B	2a	2	2	N	N
84092	Gynecological Laparoscopic Kit	B	2a	2	2	N	N
84093	Heater, Perineal	B	2a	2	2	N	N
84094	Heater, Perineal, Direct Contact	C	2b	3	2	N	N
84095	Heater, Perineal, Radiant, Non-Contact	B	2a	2	2	N	N
84096	Hemorrhoid Prevention Pressure Wedge	B	2a	2	2	N	N
84097	Holograph, Fetal, Acoustical	D	3	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84098	Home Uterine Activity Monitor	B	2a	2	2	N	N
84099	Hook, Destructive, Obstetrical	B	2a	2	2	N	N
84100	Hook, Fibroid, Gynecological	A	1	1	1	N	N
84101	Hysterectomy Kit	B	2a	2	2	N	N
84102	Hysteroscope (And Accessories)	B	2a	2	2	N	N
84103	Hysteroscope Accessories	B	3	2	1	N	N
84104	Imager, Ultrasonic Obstetric-Gynecologic	C	2b	3	2	N	N
84105	Insert, Tubal Occlusion	C	2b	3	3	Y	N
84106	Instrument, Destructive, Fetal, Obstetric	A	1	1	2	N	N
84107	Instrument, Manual, General Obstetric-Gynecologic	A	1	1	1	N	N
84108	Instrument, Manual, Specialized Obstetric-Gynecologic	A	1	1	2	N	N
84109	Insufflator, Carbon-Dioxide, Uterotubal (And Accessories)	B	2a	2	2	N	N
84110	Insufflator, Endoscopic Vessel Harvesting	B	2a	2	2	N	N
84111	Insufflator, Hysteroscopic	B	2a	2	2	N	N
84112	Insufflator, Laparoscopic	B	2a	2	2	N	N
84113	Insufflator, Vaginal	B	2a	2	1	N	N
84114	Intrauterine Tamponade Balloon	C	2b	3	2	N	N
84115	Kit, Conception-Assist, Home Use	B	2a	2	2	N	N
84116	Kit, Pelvic Exam	B	2a	2	U	N	N
84117	Knife, Cervical Cone	B	2a	2	2	N	N
84118	Labor And Delivery Kit	B	2a	2	U	N	N
84119	Labware, Assisted Reproduction	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84120	Laparoscope And Accessories, Gynecologic, Reprocessed	B	2a	2	2	N	N
84121	Laparoscope, Gynecologic (And Accessories)	B	2a	2	2	N	N
84122	Laparoscopic Accessories, Gynecologic	B	2a	2	1	N	N
84123	Laparoscopic Bladder-Neck Suspension Instrument, Stress Urinary Incontinence	B	2a	2	2	N	N
84124	Laparoscopic Insufflator And Accessories, Reprocessed	B	2a	2	1	N	N
84125	Laser, Neodymium:Yag For Gynecologic Use	C	2b	3	2	N	N
84126	Laser, Surgical, Gynecologic	C	2b	3	2	N	N
84127	Locator, Intracorporeal Device, Ultrasonic, Obstetric-Gynecologic	B	2a	2	2	N	N
84128	Lubricant, Personal	B	2a	2	2	N	N
84129	Material, Implant, Uterine, For Adhesiogenic Effect	C	2b	3	U		N
84130	Media, Reproductive	B	2a	2	2	N	N
84131	Micro-Condom	B	2a	2	3	N	N
84132	Micromanipulators And Microinjectors, Assisted Reproduction	B	2a	2	2	N	N
84133	Microscope And Microscope Accessories, Reproduction, Assisted	A	1	1	1	N	N
84134	Microtool Fabrication, Assisted Reproduction	B	2a	2	2	N	N
84135	Microtools, Assisted Reproduction (Pipettes)	B	2a	2	2	N	N
84136	Mold, Vaginal	B	2a	2	2	N	N
84137	Monitor, Blood-Flow, Ultrasonic	C	2b	3	2	N	N
84138	Monitor, Cardiac, Fetal	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84139	Monitor, Electroencephalographic, Fetal (And Accessories)	C	2b	3	3	N	N
84140	Monitor, Fetal Doppler Ultrasound	C	2b	3	2	N	N
84141	Monitor, Fetal Ph	C	2b	3	3	N	N
84142	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use)	D	3	2	2	N	N
84143	Monitor, Heart Rate, Fetal, Ultrasonic	C	2b	3	2	N	N
84144	Monitor, Heart Sound, Fetal, Ultrasonic	C	2b	3	2	N	N
84145	Monitor, Heart-Valve Movement, Fetal, Ultrasonic	C	2b	3	2	N	N
84146	Monitor, Hemic Sound, Ultrasonic	C	2b	3	2	N	N
84147	Monitor, Phonocardiographic, Fetal	B	2a	2	2	N	N
84148	Monitor, Pressure, Arterial, Fetal, Ultrasonic	C	2b	3	2	N	N
84149	Monitor, Pressure, Intrauterine	C	2b	3	2	N	N
84150	Monitor, Ultrasonic, Fetal	C	2b	3	2	N	N
84151	Monitor, Uterine Contraction, External (For Use In Clinic)	C	2b	3	2	N	N
84152	Needle, Aspiration, Oocyte, Reprocessed	B	2a	2	U		zz
84153	Needle, Assisted Reproduction	B	2a	2	2	N	N
84154	Needle, Cerclage, Gynecological	B	2a	2	1	N	N
84155	Needle, Reproduction, Assisted, Reprocessed	B	2a	2	2	N	N
84156	Obstetrical Kit	B	2a	2	2	N	N
84157	Obstetrical Vacuum Delivery Kit	B	2a	2	2	N	N
84158	Obstetrics And Gynecology Trocar Kit	B	2a	2	2	N	N
84159	Oximeter, Fetal Pulse	C	2b	3	3	N	N
84160	Packer, Uterine	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84161	Pad, Interlabial	A	1	1	1	N	N
84162	Pad, Menstrual, Reusable	A	1	1	1	N	N
84163	Pad, Menstrual, Scented	B	2a	2	2	N	N
84164	Pad, Menstrual, Unscented	A	1	1	1	N	N
84165	Pads, Menstrual, Scented-Deodorized	A	1	1	1	N	N
84166	Pap Smear Kit	B	2a	2	2	N	N
84167	Pelvimeter, External	A	1	1	1	N	N
84168	Pelvimeter, Internal	B	2a	2	2	N	N
84169	Perineometer	B	2a	2	2	N	N
84170	Pessary, Vaginal	B	3	2	2	N	N
84171	Prosthesis, Fallopian Tube	C	3	3	2	Y	N
84172	Prosthesis, Suture, Cerclage	C	3	3	3	N	N
84173	Pump, Breast, Non-Powered	A	3	1	1	N	N
84174	Pump, Breast, Powered	B	3	2	2	N	N
84175	Recorder, Pressure, Intrauterine	B	3	2	2	N	N
84176	Remover, Intrauterine Device, Contraceptive, Hook-Type	A	3	1	1	N	N
84177	Retractor, Vaginal	A	3	1	1	N	N
84178	Sampler, Amniotic Fluid (Amniocentesis Tray)	B	3	2	1	N	N
84179	Sampler, Blood, Fetal	B	3	2	2	N	N
84180	Scissors, Episiotomy	A	1	1	1	N	N
84181	Scissors, Umbilical	A	3	1	1	N	N
84182	Screw, Fibroid, Gynecological	B	3	2	2	N	N
84183	Seminal Fluid Collection Kit	B	3	2	2	N	N
84184	Sensor,Electro-Optical(For Cervical Cancer)	C	3	3	3	N	N
84185	Set, Anesthesia, Obstetric	B	3	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84186	Set, Anesthesia, Paracervical	B	3	2	2	N	N
84187	Set, Anesthesia, Pudendal	B	3	2	2	N	N
84188	Sheet, Recording, Breast Examination	D	3	2	2	N	N
84189	Shield, Circumcision	A	3	1	2	N	N
84190	Sound, Uterine	B	3	2	1	N	N
84191	Source, Abortion Unit, Vacuum	B	3	2	2	N	N
84192	Source, Chemiluminescent Light	B	3	2	2	N	N
84193	Spatula, Cervical, Cytological	A	3	1	2	N	N
84194	Speculum, Vaginal, Metal	A	3	1	1	N	N
84195	Speculum, Vaginal, Metal, Fiberoptic	A	1	1	1	N	N
84196	Speculum, Vaginal, Nonmetal	B	2a	2	2	N	N
84197	Speculum, Vaginal, Nonmetal, Fiberoptic	B	2a	2	2	N	N
84198	Spermatocele, Alloplastic	C	2b	3	U	Y	N
84199	Stent, Vaginal	B	3	2	2	N	N
84200	Stent,Bladder,Fetal	C	2b	3	f	Y	Y
84201	Stethoscope, Fetal	A	1	1	1	N	N
84202	Stimulator, Fetal, Acoustic	C	2b	3	3	N	N
84203	Stimulator, Vaginal, Muscle, Powered, For Therapeutic Use	C	2b	3	3	N	N
84204	System, Abortion, Metreurynter-Balloon	C	2b	3	3	N	N
84205	System, Abortion, Vacuum	B	2a	2	2	N	N
84206	System, Assisted Reproduction Laser	C	2b	3	2	N	N
84207	System, Documentation, Breast Lesion	B	2a	2	2	N	N
84208	System, Intrafallopian Cannula	B	2a	2	U	N	N
84209	System, Monitoring, For Progress Of Labor	C	2b	3	2	N	N
84210	System, Monitoring, Perinatal	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84211	System, Telethermographic (Adjunctive Use)	C	2b	3	1	N	N
84212	System, Telethermographic (Sole Diagnostic Screen)	C	2b	3	3	N	N
84213	System, Telethermographic, Infrared	C	2b	3	3	N	N
84214	System, Thermographic, Liquid Crystal	C	2b	3	1	N	N
84215	System, Thermographic, Liquid Crystal (Sole Diagnostic Screen)	C	2b	3	3	N	N
84216	System, Thermographic, Liquid Crystal, Nonpowered (Adjunctive Use)	C	2b	3	1	N	N
84217	System, Thermographic, Liquid Crystal, Powered (Adjunctive Use)	C	2b	3	3	N	N
84218	System, Water, Reproduction, Assisted, And Purification	C	2b	3	2	N	N
84219	Table, Obstetric (And Accessories)	A	1	1	2	N	N
84220	Table, Obstetrical, Ac-Powered (And Accessories)	A	1	1	2	N	N
84221	Table, Obstetrical, Manual (And Accessories)	A	1	1	2	N	N
84222	Tampon, Menstrual, Scented, Deodorized	B	2a	2	2	N	N
84223	Tampon, Menstrual, Unscented	B	2a	2	2	N	N
84224	Tenaculum, Uterine	A	1	1	2	N	N
84225	Test, Cervical Mucus Penetration	B	2a	2	U	N	N
84226	Transducer, Pressure, Intrauterine	B	2a	2	2	N	N
84227	Transducer, Ultrasonic, Obstetric	C	2b	3	2	N	N
84228	Tubing And Tubing/Filter Fits	A	1	1	1	N	N
84229	Tubing/Tubing With Filter, Insufflation, Laparoscopic	B	2a	2	1	N	N
84230	Uterine Electromyographic Monitor	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
884 OBSTETRICAL AND GYNECOLOGICAL DEVICES9							
84231	Vaginoscope And Accessories	B	2a	2	2	N	N
84232	Valve, Tubal Occlusion	C	2b	3	3	Y	N
84233	Vibrator For Therapeutic Use, Genital	B	2a	2	2	N	N
84234	Viscometer, Mucus, Cervical	A	1	1	1	N	N
84235	Washer, Endometrial	B	2a	2	2	N	N
84236	Water Immersion Labor Pool	A	1	1	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
886 OPHTHALMIC DEVICES							
86001	Aberrometer, Ophthalmic	B	2a	2	1	N	N
86002	Accessories, Soft Lens Products	B	2a	2	2	N	N
86003	Accessories, Solution, Ultrasonic Cleaners For Lenses	B	2a	2	2	N	N
86004	Adaptometer (Biophotometer)	A	1	1	1	N	N
86005	Adaptometer (Biophotometer), Software-Based Data Acquisition And Stimulus Generation	A	1	1	1	N	N
86006	Aid, Surgical, Viscoelastic	C	2b	3	3	N	N
86007	Aid, Vision Image Intensification	A	1	1	1	N	N
86008	Aid, Vision, Electronic, Ac-Powered	A	1	1	1	N	N
86009	Aid, Vision, Electronic, Battery-Powered	A	1	1	1	N	N
86010	Aid, Vision, Optical, Ac-Powered	A	1	1	1	N	N
86011	Aid, Vision, Optical, Battery-Powered	A	1	1	1	N	N
86012	Anomaloscope	A	1	1	1	N	N
86013	Apparatus, Cautery, Radiofrequency, Ac-Powered	C	2b	3	2	N	N
86014	Apparatus, Cautery, Radiofrequency, Battery-Powered	C	2b	3	2	N	N
86015	Apparatus, Cutting, Radiofrequency, Electrosurgical, Battery-Powered	C	2b	3	2	N	N
86016	Applicator, Ocular Pressure	A	1	1	2	N	N
86017	Biomicroscope, Slit-Lamp, Ac-Powered	A	1	1	2	N	N
86018	Blade, Keratome, Reprocessed	B	2a	2	1	N	N
86019	Brush, Haidinger, (Including Macular Integrity)	A	1	1	1	N	N
86020	Burr, Corneal, Ac-Powered	B	2a	2	1	N	N
86021	Burr, Corneal, Ac-Powered, Rust Ring Removal	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
886 OPHTHALMIC DEVICES							
86022	Burr, Corneal, Battery Powered, Rust Ring Removal	B	2a	2	1	N	N
86023	Burr, Corneal, Battery-Powered	B	2a	2	1	N	N
86024	Burr, Corneal, Manual	A	1	1	1	N	N
86025	Button, Iris, Eye, Artificial	B	2a	2	1	N	N
86026	Cabinet, Instrument, Ac-Powered, Ophthalmic	A	1	1	1	N	N
86027	Calibrator, Tonometer	B	2a	2	2	N	N
86028	Caliper, Ophthalmic	A	1	1	1	N	N
86029	Camera, Ophthalmic, Ac-Powered	B	2a	2	2	N	N
86030	Campimeter, Stereo, Battery-Powered	A	1	1	1	N	N
86031	Cannula, Ophthalmic	B	2a	2	1	N	N
86032	Cannula, Trocar, Ophthalmic	D	3	2	1	N	N
86033	Cannula, Ophthalmic, Posterior Capsular Polishing, Polyvinyl Acetal	B	2a	2	1	N	N
86034	Case, Contact Lens	A	1	1	2	N	N
86035	Catheter, Balloon For Retinal Reattachment	B	2a	2	3	N	N
86036	Chair, Ophthalmic, Ac-Powered	A	1	1	1	N	N
86037	Chair, Ophthalmic, Manual	A	1	1	1	N	N
86038	Chart, Visual Acuity	A	1	1	1	N	N
86039	Clamp, Eyelid, Ophthalmic	A	1	1	1	N	N
86040	Clamp, Muscle, Ophthalmic	A	1	1	1	N	N
86041	Clip, Iris Retractor	A	1	1	1	N	N
86042	Clip, Lens, Trial, Ophthalmic	A	1	1	1	N	N
86043	Clip, Tantalum, Ophthalmic	C	2b	3	2	Y	N
86044	Collagen Corneal Shield	D	3	4	1	N	N
86045	Compressor, Orbital	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
886 OPHTHALMIC DEVICES							
86046	Conformer, Ophthalmic	B	2a	2	2	N	N
86047	Conformer, Ophthalmic, Biological Tissue	B	2a	2	2	Y	N
86048	Crutch, Ptosis	A	1	1	1	N	N
86049	Cup, Eye	B	2a	2	U	N	N
86050	Curette, Ophthalmic	B	2a	2	1	N	N
86051	Cystotome	B	2a	2	1	N	N
86052	Depressor, Orbital	A	1	1	1	N	N
86053	Device, Fixation, Ac-Powered, Ophthalmic	A	1	1	1	N	N
86054	Device, Irrigation, Ocular Surgery	B	2a	2	1	N	N
86055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	A	1	1	1	N	N
86056	Device,Analysis,Anterior Segment	B	2a	2	2	N	N
86057	Dilator, Expansive Iris (Accessory)	B	2a	2	2	N	N
86058	Dilator, Lachrymal	D	3	2	1	N	N
86059	Distometer	A	1	1	1	N	N
86060	Drum, Eye Knife Test	A	1	1	1	N	N
86061	Drum, Opticokinetic	A	1	1	1	N	N
86062	Electrode, Corneal	B	2a	2	2	N	N
86063	Electrosurgical, Radio Frequency, Refractive Correction	D	3	3	3	N	N
86064	Engine, Trephine, Accessories, Ac-Powered	B	2a	2	1	N	N
86065	Engine, Trephine, Accessories, Battery-Powered	B	2a	2	1	N	N
86066	Engine, Trephine, Accessories, Gas-Powered	B	2a	2	1	N	N
86067	Erisophake	A	1	1	1	N	N
86068	Esthesiometer, Ocular	B	2a	2	1	N	N
86069	Euthyscope, Ac-Powered	A	1	1	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
886 OPHTHALMIC DEVICES							
86070	Euthyscope, Battery-Powered	A	1	1	1	N	N
86071	Excimer Laser System	C	2b	3	3	N	N
86072	Exophthalmometer	B	2a	2	1	N	N
86073	Expander, Tissue, Orbital	B	2a	2	2	Y	N
86074	Expressor	A	1	1	1	N	N
86075	Eye Tray	B	2a	2	2	N	N
86076	Eye, Artificial, Non-Custom	B	2a	2	1	N	N
86077	Eyelid Thermal Pulsation System	B	2a	2	2	N	N
86078	Fixation, Vision Training, Binocular	A	1	1	1	N	N
86079	Flasher, Afterimage, Ophthalmic	B	3	2	2	N	N
86080	Fluid, Intraocular	C	2b	3	3	N	N
86081	Fluidic, Phacoemulsification/Phacofragmentation	C	2b	3	2	N	N
86082	Folders And Injectors, Intraocular Lens (Iol)	B	2a	2	1	N	N
86083	Forceps, Ophthalmic	B	2a	2	1	N	N
86084	Fornixscope	A	1	1	1	N	N
86085	Frame, Spectacle	D	3	1	1	N	N
86086	Frame, Trial, Ophthalmic	A	1	1	1	N	N
86087	Gases Used Within Eye To Place Pressure On Detached Retina	C	2b	3	3	N	N
86088	Gauge, Lens, Ophthalmic	D	3	1	1	N	N
86089	Graft Insertion Instrument For Endothelial Keratoplasty	D	3	2	1	N	N
86090	Graft, Sclera, Reinforcement	C	2b	3	3	Y	N
86091	Grid, Amsler	A	1	1	1	N	N
86092	Haploscope	A	1	1	1	N	N

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886 OPHTHALMIC DEVICES							
86093	Headlamp, Operating, Ac-Powered	A	1	1	2	N	N
86094	Headlamp, Operating, Battery-Operated	A	1	1	1	N	N
86095	Headlight, Fiberoptic Focusing	A	1	1	2	N	N
86096	Hook, Ophthalmic	D	3	2	1	N	N
86097	Illuminator, Color Vision Plate	A	1	1	1	N	N
86098	Implant, Absorbable, (Scleral Buckling Methods)	C	2b	3	2	Y	N
86099	Implant, Corneal, Refractive	D	3	4	f	Y	N
86100	Implant, Eye Sphere	C	2b	3	2	Y	N
86101	Implant, Eye Valve	C	2b	3	2	Y	N
86102	Implant, Orbital, Extra-Ocular	C	3	3	2	Y	N
86103	Injector, Capsular Tension Ring	C	2b	3	1	N	N
86104	Insertor/Remover Contact Lens	A	1	1	1	N	N
86105	Instrument, Measuring, Corneal Radius	A	1	1	1	N	N
86106	Instrument, Measuring, Lens, Ac-Powered	A	1	1	1	N	N
86107	Instrument, Measuring, Stereopsis	A	1	1	1	N	N
86108	Instrument, Visual Field, Laser	B	2a	2	2	N	N
86109	Instrument, Vitreous Aspiration And Cutting, Ac-Powered	C	2b	3	2	N	N
86110	Instrument, Vitreous Aspiration And Cutting, Battery-Powered	C	2b	3	2	N	N
86111	Intraocular Lens	C	2b	3	3	Y	N
86112	Intraocular Pressure Lowering Implant	C	2b	3	3	Y	N
86113	Intraocular, Pressure Measuring Device	C	2b	3	3	N	N
86114	Introducer, Sphere	A	1	1	1	N	N
86115	Keratome, Ac-Powered	B	2a	2	1	N	N
86116	Keratome, Battery-Powered	B	2a	2	1	N	N

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886 OPHTHALMIC DEVICES							
86117	Keratome,Water Jet	B	2a	2	1	N	N
86118	Keratoprosthesis, Permanent Implant	C	2b	3	2	Y	N
86119	Keratoprosthesis, Temporary Implant, Surgical Use	C	2b	3	2	Y	N
86120	Keratoscope, Ac-Powered	A	1	1	1	N	N
86121	Keratoscope, Battery-Powered	A	1	1	1	N	N
86122	Knife, Ophthalmic	B	2a	2	1	N	N
86123	Knife, Ophthalmic, Reprocessed	B	2a	2	1	N	N
86124	Lacrimal Stents And Intubation Sets	C	2b	3	U	Y	N
86125	Laser, Neodymium:Yag, Ophthalmic For Posterior Capsulotomy And Cutting Pupilla	C	2b	3	2	N	N
86126	Laser, Neodymium:Yag, Ophthalmic For Uses Other Than Posterior Capsulotomy & Cutting Pupillary	C	2b	3	3	N	N
86127	Laser, Ophthalmic	C	2b	3	2	N	N
86128	Laser,System,Phacolysis	C	2b	3	2	N	N
86129	Lens, Bagolini	A	1	1	1	N	N
86130	Lens, Condensing, Diagnostic	A	1	1	1	N	N
86131	Lens, Contact (Orthokeratology)	B	2a	2	2	N	N
86132	Lens, Contact (Other Material) - Daily	B	2a	2	2	N	N
86133	Lens, Contact (Polymethylmethacrylate)	B	2a	2	U	N	N
86134	Lens, Contact, (Disposable)	B	2a	2	2	N	N
86135	Lens, Contact, For Color Vision Deficiency	B	2a	2	2	N	N
86136	Lens, Contact, For Reading Discomfort	B	2a	2	2	N	N
86137	Lens, Contact, Orthokeratology, Overnight	C	2b	3	3	N	N

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886 OPHTHALMIC DEVICES							
86138	Lens, Contact, Polymethylmethacrylate, Diagnostic	B	2a	2	2	N	N
86139	Lens, Fresnel, Flexible, Diagnostic	A	1	1	1	N	N
86140	Lens, Fundus, Hruby, Diagnostic	A	1	1	1	N	N
86141	Lens, Guide, Intraocular	D	3	2	1	N	N
86142	Lens, Intraocular, Phakic	C	2b	3	3	Y	N
86143	Lens, Intraocular, Toric Optics	C	2b	3	3	Y	N
86144	Lens, Iris Reconstruction	C	2b	3	3	Y	N
86145	Lens, Maddox	A	1	1	1	N	N
86146	Lens, Multifocal Intraocular	C	2b	3	3	N	N
86147	Lens, Spectacle (Prescription), For Reading Discomfort	B	2a	2	1	N	N
86148	Lens, Spectacle, Non-Custom (Prescription)	A	1	1	1	N	N
86149	Lens, Surgical, Laser, Accessory, Ophthalmic Laser	B	2a	2	2	N	N
86150	Lens, Contact (Rigid Gas Permeable)-Extended Wear	C	2b	3	3	N	N
86151	Lens, Intraocular, Accommodative	C	2b	3	3	Y	N
86152	Lens, Prescription, Color Deficiency	A	1	1	1	N	N
86153	Lenses, Soft Contact, Daily Wear	B	2a	2	2	N	N
86154	Lenses, Soft Contact, Extended Wear	B	2a	2	3	N	N
86155	Light, Headband, Surgical	A	1	1	2	N	N
86156	Locator, Magnetic	A	1	1	1	N	N
86157	Locator, Metal, Electronic	B	2a	2	2	N	N
86158	Loupe, Binocular, Low Power	A	1	1	1	N	N
86159	Magnet, Ac-Powered	B	2a	2	2	N	N

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886 OPHTHALMIC DEVICES							
86160	Magnet, Permanent	A	1	1	1	N	N
86161	Magnifier, Hand-Held, Low-Vision	A	1	1	1	N	N
86162	Marker, Ocular	B	2a	2	1	N	N
86163	Marker, Sclera	B	2a	2	1	N	N
86164	Maxwell Spot, Ac-Powered	B	2a	2	1	N	N
86165	Media, Corneal Storage	C	2b	3	U	N	N
86166	Microscope, Specular	B	2a	2	2	N	N
86167	Mirror, Headband, Ophthalmic	A	1	1	1	N	N
86168	Monitor, Eye Movement	B	2a	2	2	N	N
86169	Monitor, Eye Movement, Diagnostic	B	3	2	2	N	N
86170	Needle, Ophthalmic Suturing	B	3	2	1	N	N
86171	Needle, Phacoemulsification, Reprocessed	B	3	2	2	N	N
86173	Ocular Peg	B	3	2	2	Y	N
86174	Ophthalmic Femtosecond Laser	C	3	3	2	N	N
86175	Ophthalmodynamometer, Diagnostic Contact Lens, Polymethylmethacrylate (Pmma)	B	3	2	2	N	N
86176	Ophthalmoscope, Ac-Powered	A	3	1	2	N	N
86177	Ophthalmoscope, Battery-Powered	A	3	1	2	N	N
86178	Ophthalmoscope,Laser,Scanning	B	3	2	2	N	N
86179	Ophthalmoscopes,Replacement Batteries,Hand-Held	A	3	1	U	N	N
86180	Pen, Marking, Surgical	B	2a	2	1	N	N
86181	Perimeter, Ac-Powered	A	3	1	1	N	N
86182	Perimeter, Automatic, Ac-Powered	A	3	1	1	N	N
86183	Perimeter, Manual	A	3	1	1	N	N
86184	Photocoagulator And Accessories	C	3	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
886 OPHTHALMIC DEVICES							
86185	Photokeratoscope	A	3	1	1	N	N
86186	Photokeratoscope, Battery Powered	A	3	1	1	N	N
86187	Photorefractor	B	3	2	2	N	N
86188	Photostimulator, Ac-Powered	D	3	2	2	N	N
86189	Plug, Punctum	C	3	3	U	N	N
86190	Plug, Scleral	B	3	2	U	N	N
86191	Preamplifier, Ac-Powered, Ophthalmic	B	3	2	2	N	N
86192	Preamplifier, Battery-Powered, Ophthalmic	B	3	2	2	N	N
86193	Prism, Bar, Ophthalmic	A	3	1	1	N	N
86194	Prism, Fresnel, Ophthalmic	A	3	1	1	N	N
86195	Prism, Gonioscopic	B	2a	2	1	N	N
86196	Prism, Rotary, Ophthalmic	A	1	1	1	N	N
86197	Probe And Counter, Isotope, For Phosphorus 32	B	2a	2	2	N	N
86198	Probe, Lachrymal	A	1	1	1	N	N
86199	Probe, Trabeculotomy	A	3	1	1	N	N
86200	Products, Contact Lens Care, Rigid Gas Permeable	B	2a	2	2	N	N
86201	Projector, Ophthalmic	A	1	1	1	N	N
86202	Prosthesis, Eyelid Spacer/Graft, Biologic	C	2b	3	2	Y	N
86203	Punch, Corneo-Scleral	A	1	1	1	N	N
86204	Pupillograph	A	1	1	1	N	N
86205	Pupillometer, Ac-Powered	A	1	1	1	N	N
86206	Pupillometer, Manual	A	1	1	1	N	N
86207	Rack, Skiascopic	A	1	1	1	N	N
86208	Reader, Bar, Ophthalmic	A	1	1	1	N	N
86209	Reader, Prism, Ophthalmic	A	1	1	1	N	N
86210	Refractive Corneal Implant	C	2b	3	f	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
886 OPHTHALMIC DEVICES							
86211	Refractometer, Ophthalmic	B	2a	2	1	N	N
86212	Refractor, Manual, Non-Powered, Including Phoropter	A	1	1	1	N	N
86213	Retinoscope, Ac-Powered	A	1	1	2	N	N
86214	Retinoscope, Battery-Powered	A	1	1	1	N	N
86215	Retractor, Ophthalmic	B	2a	2	1	N	N
86216	Ring, Endocapsular	C	2b	3	3	Y	N
86217	Ring, Ophthalmic (Flieringa)	A	1	1	1	N	N
86218	Rongeur, Lachrymal Sac	A	1	1	1	N	N
86219	Ruler, Nearpoint (Punctometer)	A	1	1	1	N	N
86220	Scissors, Ophthalmic	B	2a	2	1	N	N
86221	Screen, Tangent, Ac-Powered (Campimeter)	A	1	1	1	N	N
86222	Screen, Tangent, Felt (Campimeter)	A	1	1	1	N	N
86223	Screen, Tangent, Projection, Ac-Powered	A	1	1	1	N	N
86224	Screen, Tangent, Projection, Battery-Powered	A	1	1	1	N	N
86225	Screen, Tangent, Target	A	1	1	1	N	N
86226	Screen, Tangent, Target, Battery-Powered	A	1	1	1	N	N
86227	Selector, Color, Spectacle, Lens, Tint	A	1	1	1	N	N
86228	Set, Lens, Trial, Ophthalmic	A	1	1	1	N	N
86229	Shell, Scleral	B	2a	2	2	Y	N
86230	Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear)	A	1	1	1	N	N
86231	Simulatan (Including Crossed Cylinder)	A	1	1	1	N	N
86232	Snare, Enucleating	A	1	1	1	N	N
86233	Solution, Cleaning/Lubricating, Artifical Eye	C	2b	3	3	N	N
86234	Spatula, Ophthalmic	A	1	1	1	N	N

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886 OPHTHALMIC DEVICES							
86235	Spectacle Microscope, Low-Vision	A	1	1	1	N	N
86236	Spectacle, Magnifying	A	1	1	1	N	N
86237	Spectacle, Operating (Loupe), Ophthalmic	A	1	1	1	N	N
86238	Specula, Ophthalmic	B	2a	2	1	N	N
86239	Sponge, Ophthalmic	B	2a	2	2	N	N
86240	Spoon, Ophthalmic	A	1	1	1	N	N
86241	Spud, Ophthalmic	A	1	1	1	N	N
86242	Stand, Instrument, Ac-Powered, Ophthalmic	A	1	1	1	N	N
86243	Stand, Instrument, Ophthalmic, Battery Powered	A	1	1	1	N	N
86244	Stand, Instrument, Ophthalmic, Non-Powered	A	1	1	1	N	N
86245	Stereoscope, Ac-Powered	A	1	1	1	N	N
86246	Stereoscope, Battery-Powered	A	1	1	1	N	N
86247	Sterilizer, Soft-Lens, Thermal, Ac-Powered	B	2a	2	2	N	N
86248	Sterilizer, Soft-Lens, Thermal, Battery-Powered	B	2a	2	2	N	N
86249	Sterilizer, Tonometer	B	2a	2	1	N	N
86250	Strip, Schirmer	B	2a	2	1	N	N
86251	Sunglasses (Non-Prescription Including Photosensitive)	A	1	1	1	N	N
86252	Suture, Absorbable, Ophthalmic	C	2b	3	3	Y	N
86253	Suture, Nonabsorbable, Ophthalmic	C	2b	3	3	Y	N
86254	System, Identification, Contact Lens	C	2b	3	3	N	N
86255	System, Reading, Television, Closed-Circuit	D	1	1	1	N	N
86256	System, In-Office Tinting, Contact Lenses	D	2a	2	2	N	N
86257	Table, Instrument, Manual, Ophthalmic	D	1	1	1	N	N
86258	Table, Instrument, Powered, Ophthalmic	D	1	1	1	N	N
86259	Tape, Nystagmus	D	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
886 OPHTHALMIC DEVICES							
86260	Target, Fusion And Stereoscopic	D	1	1	1	N	N
86261	Telescope, Hand-Held, Low-Vision	D	1	1	1	N	N
86262	Telescope, Implantable, Miniature	D	2b	3	3	Y	N
86263	Telescope, Spectacle, Low-Vision	A	1	1	1	N	N
86264	Test, Spectacle Dissociation, Ac-Powered (Lancaster)	A	1	1	1	N	N
86265	Test, Spectacle Dissociation, Battery-Powered (Lancaster)	A	1	1	1	N	N
86266	Tester, Color Vision	A	1	1	1	N	N
86267	Tissue Adhesive For Ophthalmic Use	C	2b	3	3	N	N
86268	Tomography, Optical Coherence	B	2a	2	2	N	N
86269	Tonograph	B	2a	2	2	N	N
86270	Tonometer, Ac-Powered	B	2a	2	2	N	N
86271	Tonometer, Analyzer, Ocular Blood Flow	B	2a	2	2	N	N
86272	Tonometer, Manual	B	2a	2	2	N	N
86273	Topographer, Corneal, Ac-Powered	B	2a	2	1	N	N
86274	Topographer, Corneal, Battery Powered	A	1	1	1	N	N
86275	Trabeculotome	A	1	1	1	N	N
86276	Transilluminator, Ac-Powered	A	1	1	2	N	N
86277	Transilluminator, Battery-Powered	A	1	1	1	N	N
86278	Trephine, Manual, Ophthalmic	B	2a	2	1	N	N
86279	Tubing, Replacement, Phacofragmentation Unit	B	2a	2	2	N	N
86280	Ultrasound, Cyclodestructive	C	2b	3	3	N	N
86281	Unit, Beta, Radiation, Ophthalmic	C	2b	3	2	N	N
86282	Unit, Cautery, Thermal, Ac-Powered	C	2b	3	2	N	N
86283	Unit, Cautery, Thermal, Battery-Powered	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
886 OPHTHALMIC DEVICES							
86284	Unit, Cryophthalmic	C	2b	3	2	N	N
86285	Unit, Cryophthalmic, Ac-Powered	C	2b	3	2	N	N
86286	Unit, Cryotherapy, Ophthalmic	C	2b	3	2	N	N
86287	Unit, Electrolysis, Ac-Powered, Ophthalmic	B	2a	2	2	N	N
86288	Unit, Electrolysis, Battery-Powered, Ophthalmic	B	2a	2	1	N	N
86289	Unit, Phacofragmentation	C	2b	3	2	N	N
86290	Vitrectomy, Instrument Cutter	C	2b	3	2	N	N
86291	Weights, Eyelid, External	B	2a	2	U	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
888 ORTHOPEDIC DEVICES							
88001	Accessories, Fixation, Spinal Interlaminar	C	2b	3	2	Y	N
88002	Accessories, Fixation, Spinal Intervertebral Body	C	2b	3	U	N	N
88003	Accessories, Arthroscopic	B	2a	2	1	N	N
88004	Accessory, System, External Fixator, Containing Antimicrobial Agent	C	2b	3	2	Y	N
88005	Acid, Hyaluronic, Intraarticular	C	2b	3	3	N	N
88006	Anchor, Suture, Bone Fixation, Metallic	C	2b	3	2	Y	N
88007	Ankle Arthroplasty Implantation System	C	2b	3	2	N	N
88008	Apparatus, Traction, Non-Powered	A	1	1	1	N	N
88009	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component	C	2b	3	2	Y	N
88010	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite	C	2b	3	2	Y	N
88011	Appliance, Fixation, Nail/Blade/Plate Combination, Single Component	C	2b	3	2	Y	N
88012	Appliance, Fixation, Spinal Interlaminar	C	2b	3	2	Y	N
88013	Appliance, Fixation, Spinal Intervertebral Body	C	2b	3	2	Y	N
88014	Appliance, Nail/Blade/Plate Combination, Single Component	C	2b	3	2	Y	N
88015	Appliances And Accessories, Fixation, Bone, Absorbable Single/Multiple Component	C	2b	3	U	Y	N
88016	Applier, Cerclage	A	1	1	1	N	N
88017	Arthrometer	U	U	U	U	N	N
88018	Arthroscope	B	2a	2	2	N	N
88019	Awl	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
888 ORTHOPEDIC DEVICES							
88020	Belt, Pelvic, Traction	A	1	1	1	N	N
88021	Bender	A	1	1	1	N	N
88022	Bit, Drill	B	2a	2	1	N	N
88024	Bone Cement, Antibiotic	C	2b	3	2	Y	N
88025	Bone Fixation Cerclage, Sublaminar	C	2b	3	2	Y	N
88026	Bone Mill	A	1	1	1	N	N
88027	Bone, Heterograft	C	2b	3	3	Y	N
88028	Brace, Drill	A	1	1	1	N	N
88029	Broach	A	1	1	1	N	N
88030	Burr, Orthopedic	B	2a	2	1	N	N
88031	Calcium Salt Bone Void Filler, Drillable, Non-Screw Augmentation	C	2b	3	2	Y	N
88032	Caliper	A	1	1	1	N	N
88033	Cap, Bone	D	3	3	1	Y	N
88034	Cement, Bone, Pre-Formed, Modular, Polymeric, Vertebroplasty	C	2b	3	2	Y	N
88035	Cement, Bone, Vertebroplasty	C	2b	3	2	Y	N
88036	Cement, Bone, Vertebroplasty, Pre-Formed, Modular	C	2b	3	2	Y	N
88037	Ceramics, Calcium Triphosphate/Hydroxyapatite, Non-Load Bearing Uses	C	2b	3	3	N	N
88038	Cerclage, Fixation	C	2b	3	2	Y	N
88039	Cerclage, Fixation, Metallic	C	2b	3	2	Y	N
88040	Component, Cast	A	1	1	1	N	N
88041	Component, Traction, Invasive	C	2b	3	2	Y	N
88042	Component, Traction, Non-Invasive	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
888 ORTHOPEDIC DEVICES							
88043	Condylar Plate Fixation Implant	C	2b	3	2	Y	N
88044	Corkscrew	A	1	1	1	N	N
88045	Countersink	A	1	1	1	N	N
88046	Crimper, Pin	A	1	1	1	N	N
88047	Cutter, Wire	A	1	1	1	N	N
88048	Device, Fixation, Proximal Femoral, Implant	C	2b	3	2	Y	N
88049	Dispenser, Cement	B	2a	2	1	N	N
88050	Driver, Prosthesis	A	1	1	1	N	N
88051	Dynamometer, Ac-Powered	B	2a	2	2	N	N
88052	Dynamometer, Nonpowered	B	2a	2	1	N	N
88053	Electronic Depth Gauge	B	2a	2	2	N	N
88054	Evacuator, Vapor, Cement Monomer	A	1	1	1	N	N
88055	Extractor	B	2a	2	1	N	N
88056	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	C	2b	3	3	Y	N
88057	Fastener, Fixation, Biodegradable, Soft Tissue	C	2b	3	2	N	N
88058	Fastener, Fixation, Nondegradable, Soft Tissue	C	2b	3	2	Y	N
88059	File	D	3	1	1	N	N
88060	Filler, Bone Void, Calcium Compound	C	2b	3	2	Y	N
88061	Filler, Bone Void, Non-Osteoinduction	C	2b	3	3	N	N
88062	Filler, Bone Void, Osteoinduction (W/O Human Growth Factor)	C	2b	3	2	Y	N
88063	Filler, Bone Void, Recombinant Platelet-Derived Growth Factor	C	2b	3	3	Y	Y

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888 ORTHOPEDIC DEVICES							
88064	Filler, Recombinant Human Bone Morphogenetic Protein, Collagen Scaffold With Metal Prosthesis, Osteoinduction	D	3	3	3	Y	N
88065	Filler, Recombinant Human Bone Morphogenetic Protein, Collagen Scaffold, Osteoinduction	D	3	4	3	N	N
88066	Filler, Recombinant Human Bone Morphogenetic Protein, Collagen Scaffold, Osteoinduction - Hde	D	3	4	U	Y	N
88067	Filler, Recombinant Human Bone Morphogenetic Protein, Collagen Scaffold, Osteoinduction - Hde, Long Bone Nonunion	D	3	4	U	Y	N
88068	Finger Semi-Constrained Pyrolytic Carbon Uncemented Prosthesis	C	2b	3	3		N
88069	Fixation Accessory	C	2b	3	2	Y	N
88070	Fork	A	1	1	1	N	N
88071	Gauge, Depth	A	1	1	1	N	N
88072	Goniometer With Electrodes	B	2a	2	2	N	N
88073	Goniometer, Ac-Powered	A	1	1	1	N	N
88074	Goniometer, Nonpowered	A	1	1	1	N	N
88075	Guide, Drill, Ligament	B	2a	2	U	N	N
88076	Halter, Head, Traction	A	1	1	1	N	N
88077	High Demand, Revision, Semi-Constrained, Pyrolytic Carbon, Uncemented Finger Prosthesis	C	2b	3	U	Y	N
88078	Hip Prosthesis, Semi-Constrained, Cemented, Metal/Polymer, + Additive, Porous, Uncemented	C	3	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88079	Hip, Semi-Constrained, Cemented, Metal/Ceramic/Polymer + Additive, Porous Uncemented	C	3	3	2	Y	N
88080	Hip, Semi-Constrained, Cemented, Metal/Polymer + Additive, Cemented	C	3	3	2	Y	N
88081	Holder, Needle; Orthopedic	A	1	1	1	N	N
88082	Impactor	A	1	1	1	N	N
88083	Implant, Cartilage, For Articular Cartilage Repair	C	2b	3	3	Y	N
88084	Implant, Fixation Device, Spinal	C	2b	3	2	Y	N
88085	Inhibitor, Peridural Fibrosis (Adhesion Barrier)	C	2b	3	3	N	N
88086	Injector, Vertebroplasty (Does Not Contain Cement)	D	3	2	1	N	N
88087	Instrument, Bending Or Contouring	A	1	1	1	N	N
88088	Instrument, Cast Application/Removal, Manual	A	1	1	1	N	N
88089	Instrument, Cast Removal, Ac-Powered	D	3	1	1	N	N
88090	Instrument, Compression	D	3	1	1	N	N
88091	Instrument, Surgical, Orthopedic, Dc-Powered Motor And Accessory/Attachment	B	2a	2	U	N	N
88092	Instrument, Surgical, Orthopedic, Pneumatic Powered & Accessory/Attachment	B	2a	2	U	N	N
88093	Instrument, Surgical, Sonic And Accessory/Attachment	B	2a	2	2	N	N
88094	Intervertebral Fusion Device With Bone Graft, Cervical	C	2b	3	2	Y	N
88095	Intervertebral Fusion Device With Bone Graft, Lumbar	C	2b	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88096	Intervertebral Fusion Device With Bone Graft, Solid-Sphere, Lumbar	C	2b	3	U	Y	N
88097	Intervertebral Fusion Device With Integrated Fixation, Cervical	D	3	3	2	Y	N
88098	Intervertebral Fusion Device With Integrated Fixation, Lumbar	C	2b	3	2	Y	N
88099	Kit, Laparoscopic, Bone Anchor, Urethropexy	C	2b	3	2	N	N
88100	Knee Arthroplasty Implantation System	B	2a	2	2	N	N
88101	Knife, Orthopedic	B	2a	2	1	N	N
88102	Ligaments And Tendons, Synthetic	C	2b	3	3	Y	N
88103	Metal Cemented Constrained Femorotibial Knee Prosthesis	C	3	3	3	Y	N
88104	Metallic Cemented Glenoid Hemi-Shoulder Prosthesis	C	3	3	3	Y	N
88105	Mixer, Cement, For Clinical Use	A	1	1	1	N	N
88106	Nail, Fixation, Bone	C	2b	3	2	Y	N
88107	Nail, Fixation, Bone, Metallic	C	2b	3	2	Y	N
88108	Orthopaedic Surgical Planning And Instrument Guides	B	2a	2	2	N	N
88109	Orthopedic Implant Material	C	2b	3	U	Y	N
88110	Orthopedic Manual Surgical Instrument	A	1	1	1	N	N
88111	Orthosis, Cervical Pedicle Screw Spinal Fixation	C	2b	3	U	Y	N
88112	Orthosis, Spinal Pedicle Fixation	C	2b	3	2	Y	N
88113	Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease	C	2b	3	3	Y	N
88114	Orthosis, Spine, Plate, Laminoplasty, Metal	C	2b	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88115	Orthosis, Spondylolisthesis Spinal Fixation	C	2b	3	2	Y	N
88116	Passer	A	1	1	1	N	N
88117	Passer, Wire, Orthopedic	B	2a	2	1	N	N
88118	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis	C	2b	3	2	Y	N
88119	Pin, Fixation, Resorbable, Hard Tissue	C	2b	3	2	Y	N
88120	Pin, Fixation, Smooth	C	2b	3	2	Y	N
88121	Pin, Fixation, Smooth, Metallic	C	2b	3	2	Y	N
88122	Pin, Fixation, Threaded	C	2b	3	2	Y	N
88123	Pin, Fixation, Threaded, Metallic	C	2b	3	2	Y	N
88124	Plate, Bone, Growth Control, Pediatric, Epiphysiodesis	C	2b	3	2	Y	Y
88125	Plate, Fixation, Bone	C	2b	3	2	Y	N
88126	Plate, Fixation, Bone, Non-Spinal, Metallic	C	2b	3	2	Y	N
88127	Positioner, Socket	A	1	1	1	N	N
88128	Posterior Metal/Polymer Spinal System, Fusion	C	2b	3	2	Y	N
88129	Probe	A	1	1	1	N	N
88130	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous Cemented, Osteophilic Finish	C	3	3	2	Y	N
88131	Prosthesis, Ankle, Cemented, Non-Constrained	C	2b	3	3	Y	N
88132	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Composite	C	2b	3	2	Y	N
88133	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer	C	2b	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88134	Prosthesis, Ankle, Uncemented, Non-Constrained	C	2b	3	3	Y	Y
88135	Prosthesis, Elbow, Constrained, Cemented	C	2b	3	2	Y	N
88136	Prosthesis, Elbow, Hemi-, Humeral, Metal	C	2b	3	3	Y	N
88137	Prosthesis, Elbow, Hemi-, Radial, Polymer	C	2b	3	2	Y	N
88138	Prosthesis, Elbow, Semi-Constrained, Cemented	C	2b	3	2	Y	N
88139	Prosthesis, Finger, Constrained, Metal, Cemented	C	2b	3	3	Y	N
88140	Prosthesis, Finger, Constrained, Metal, Uncemented	C	2b	3	3	Y	N
88141	Prosthesis, Finger, Constrained, Metal/Polymer	C	2b	3	3	Y	N
88142	Prosthesis, Finger, Constrained, Polymer	D	3	3	2	Y	N
88143	Prosthesis, Finger, Polymer	C	2b	3	2	Y	N
88144	Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer	C	3	3	2	Y	N
88145	Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer, + Additive	C	3	3	2	Y	N
88146	Prosthesis, Hip, Constrained, Metal	C	3	3	3	Y	N
88147	Prosthesis, Hip, Femoral Component, Cemented, Metal	C	3	3	2	Y	N
88148	Prosthesis, Hip, Femoral, Resurfacing	C	3	3	2	Y	N
88149	Prosthesis, Hip, Hemi-, Acetabular, Cemented, Metal	C	3	3	3	Y	N
88150	Prosthesis, Hip, Hemi-, Femoral, Metal	C	3	3	2	Y	N
88151	Prosthesis, Hip, Hemi-, Femoral, Metal Ball	C	3	3	2	Y	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
888 ORTHOPEDIC DEVICES							
88152	Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented	C	3	3	2	Y	N
88153	Prosthesis, Hip, Hemi-, Trunion-Bearing, Femoral, Metal/Polyacetal	C	3	3	N	Y	N
88154	Prosthesis, Hip, Pelvifemoral Resurfacing, Metal/Polymer	C	3	3	3	Y	N
88155	Prosthesis, Hip, Pelvifemoral Resurfacing, Metal/Polymer, Uncemented	C	3	3	3	Y	N
88156	Prosthesis, Hip, Semi-Constrained (Metal Cemented Acetabular Component)	C	3	3	3	Y	N
88157	Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component)	C	3	3	3	Y	N
88158	Prosthesis, Hip, Semi-Constrained, Composite/Metal	C	3	3	2	Y	N
88159	Prosthesis, Hip, Semi-Constrained, Ceramic-On-Metal Articulation	C	3	3	3	Y	N
88160	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Ceramic, Cemented	C	3	3	3	Y	N
88161	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Ceramic/Metal, Cemented Or Uncemented	C	3	3	3	Y	N
88162	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented	C	3	3	2	Y	N
88163	Prosthesis, Hip, Semi-Constrained, Metal/Metal, Resurfacing	C	3	3	3	Y	N

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888 ORTHOPEDIC DEVICES							
88164	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented	C	3	3	2	Y	N
88165	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented	C	3	3	2	Y	N
88166	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented	C	3	3	2	Y	N
88167	Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate	C	3	3	2	Y	N
88168	Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Porous	C	3	3	2	Y	N
88169	Prosthesis, Intervertebral Disc	C	2b	3	3	Y	N
88170	Prosthesis, Knee Patellofemorotibial, Partial, Semi-Constrained, Cemented, Polymer/Metal/Polymer	C	3	3	2	Y	N
88171	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer	C	3	3	2	Y	N
88172	Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer	C	3	3	2	Y	N
88173	Prosthesis, Knee, Femorotibial, Non-Constrained, Metal/Composite Cemented	C	3	3	2	Y	N
88174	Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Composite	C	3	3	2	Y	N
88175	Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer	C	3	3	2	Y	N
88176	Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Trunion-Bearing	C	3	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88177	Prosthesis, Knee, Femorotibial, Semi-Constrained, Unicompartmental/Unicondylar, Uncemented, Porous-Coated, Metal/Polymer	C	3	3	2	Y	N
88178	Prosthesis, Knee, Femorotibial, Unicompartmental, Semi-Constrained, Metal/Polymer, Mobile Bearing	C	3	3	3	Y	N
88179	Prosthesis, Knee, Hemi-, Femoral	C	3	3	3	Y	N
88180	Prosthesis, Knee, Hemi-, Femoral (Uncemented)	C	2b	3	3	N	N
88181	Prosthesis, Knee, Hemi-, Patellar Resurfacing, Uncemented	C	3	3	2	Y	N
88182	Prosthesis, Knee, Hemi-, Tibial, Resurfacing (Uncemented)	C	3	3	2	Y	N
88183	Prosthesis, Knee, Hinged (Metal-Metal)	C	3	3	3	Y	N
88184	Prosthesis, Knee, Non-Constrained (Metal-Carbon Reinforced Polyethylene) Cemented	C	3	3	2	Y	N
88185	Prosthesis, Knee, Patello/Femoral, Semi-Constrained, Cemented, Metal/Polymer	C	3	3	2	Y	N
88186	Prosthesis, Knee, Patello/Femorotibial, Constrained, Cemented, Polymer/Metal/Metal	C	3	3	3	Y	N
88187	Prosthesis, Knee, Patello/Femorotibial, Constrained, Cemented, Polymer/Metal/Polymer	C	3	3	2	Y	N
88188	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uhmwpe, Pegged, Cemented, Polymer/Metal/Polymer	D	3	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88189	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Polymer/Metal/Polymer	C	3	3	3	Y	N
88190	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer	C	3	3	2	Y	N
88191	Prosthesis, Knee, Patello/Femorotibial, Unconstrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer	C	3	3	3	Y	N
88192	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive	C	3	3	2	Y	N
88193	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer	C	3	3	2	Y	N
88194	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Metal/Polymer, Mobile Bearing	C	3	3	3	Y	N
88195	Prosthesis, Ligament	C	2b	3	3	N	N
88196	Prosthesis, Ligament, Ptfе	C	2b	3	3	Y	N
88197	Prosthesis, Rib Replacement	C	2b	3	f	Y	N
88198	Prosthesis, Shoulder, Constrained, Metal/Metal Or Metal/Polymer Cemented	C	3	3	3	Y	N
88199	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented	C	3	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88200	Prosthesis, Shoulder, Humeral (Bipolar Hemi-Shoulder) Metal/Polymer, Cemented Or Uncemented	C	3	3	3	Y	N
88201	Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented	C	3	3	2	Y	N
88202	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer + Additive, Cemented	C	3	3	2	Y	N
88203	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	C	3	3	2	Y	N
88204	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented	C	3	3	2	Y	N
88205	Prosthesis, Spinous Process Spacer/Plate	C	2b	3	3	Y	N
88206	Prosthesis, Subtalar, Plug, Polymer	C	2b	3	U	Y	N
88207	Prosthesis, Tendon, Passive	C	2b	3	2	Y	N
88208	Prosthesis, Toe (Metatarsophalangeal), Joint, Metal/Polymer, Semi-Constrained	C	2b	3	U	Y	N
88209	Prosthesis, Toe, Constrained, Polymer	C	2b	3	2	Y	N
88210	Prosthesis, Toe, Hemi-, Phalangeal	C	2b	3	2	Y	N
88211	Prosthesis, Upper Femoral	C	2b	3	2	Y	N
88212	Prosthesis, Wrist, 2 Part Metal-Plastic Articulation, Semi-Constrained	C	2b	3	2	Y	N
88213	Prosthesis, Wrist, 3 Part Metal-Plastic-Metal Articulation, Semi-Constrained	C	2b	3	2	Y	N
88214	Prosthesis, Wrist, Carpal Lunate	C	2b	3	2	Y	N
88215	Prosthesis, Wrist, Carpal Scaphoid	C	2b	3	2	Y	N
88216	Prosthesis, Wrist, Carpal Trapezium	C	2b	3	2	Y	N

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888 ORTHOPEDIC DEVICES							
88217	Prosthesis, Wrist, Constrained, Metal	C	2b	3	3	Y	N
88218	Prosthesis, Wrist, Constrained, Polymer	C	2b	3	2	Y	N
88219	Prosthesis, Wrist, Hemi-, Ulnar	C	2b	3	2	Y	N
88220	Prosthesis, Wrist, Semi-Constrained	C	2b	3	2	Y	N
88221	Prosthetic Disc Nucleus Device	C	2b	3	3	Y	N
88222	Protractor	A	1	1	1	N	N
88223	Punch, Femoral Neck	A	1	1	1	N	N
88224	Pusher, Socket	A	1	1	1	N	N
88225	Reamer	B	2a	2	1	N	N
88226	Resorbable Spinal Intervertebral Body Fixation Orthosis - Mesh	C	2b	3	2	Y	N
88227	Resorbable Spinal Intervertebral Body Fixation Orthosis - Plate	C	2b	3	2	Y	N
88228	Rod, Fixation, Intramedullary And Accessories	C	2b	3	2	Y	N
88229	Rod, Fixation, Intramedullary And Accessories, Metallic And Non-Collapsible	C	2b	3	2	Y	N
88230	Rongeur	A	1	1	1	N	N
88231	Sacroiliac Joint Fixation	C	2b	3	2	Y	N
88232	Scissors, Orthopedic, Surgical	A	1	1	1	N	N
88233	Screw, Fixation, Bone	C	2b	3	2	Y	N
88234	Screw, Fixation, Bone, Non-Spinal, Metallic	C	2b	3	2	Y	N
88235	Screwdriver	B	2a	2	1	N	N
88236	Screwdriver, Surgical	A	1	1	U	N	N
88237	Semi-Constrained Metal/Polymer Finger Joint Prosthesis	C	2b	3	f	Y	N
88238	Set, Hollow Mill	A	1	1	1	N	N

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888 ORTHOPEDIC DEVICES							
88239	Skid, Bone	A	1	1	1	N	N
88240	Software For Diagnosis/Treatment	B	2a	2	2	Y	N
88241	Spacer, Cement	C	2b	3	3	Y	N
88242	Spinal Channeling Instrument, Vertebroplasty	B	2a	2	1	N	N
88243	Spinal Pedicle Screw, Fixation, Appliance System	C	2b	3	3	Y	N
88244	Spinal Vertebral Body Replacement Device	C	2b	3	2	Y	N
88245	Splint, Traction	A	1	1	1	N	N
88246	Staple Driver	A	1	1	1	N	N
88247	Staple, Absorbable	C	2b	3	2	Y	N
88248	Staple, Fixation, Bone	C	2b	3	2	Y	N
88249	Staple, Fixation, Bone, Metallic	C	2b	3	2	Y	N
88250	Starter, Bone Screw	A	1	1	1	N	N
88251	Stimulator, Bone Growth, Non-Invasive	B	2a	2	3	N	N
88253	Stimulator, Osteogenesis, Electric, Battery-Operated, Invasive	C	2b	3	3	N	N
88254	Stripper, Surgical	A	1	1	1	N	N
88255	System, Cement Removal Extraction	C	2b	3	2	N	N
88256	System, External Fixator (With Metallic Invasive Components)	D	2b	3	2	Y	N
88257	System, Facet Screw Spinal Device	D	2b	3	U	Y	N
88258	Tamp	D	1	1	1	N	N
88259	Tap, Bone	D	2a	2	1	N	N
88260	Template	D	1	1	1	N	N
88261	Tester, Stiffness, Cartilage, Arthroscopic	D	2a	2	2	N	N
88262	Trephine	D	2a	2	1	N	N
88263	Tube, Cement Ventilation	D	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
888 ORTHOPEDIC DEVICES							
88264	Twister, Wire	A	1	1	1	N	N
88265	Unit, Traction, Hip, Non-Powered, Non-Penetrating	A	1	1	1	N	N
88266	Vertebroplasty Compound, Calcium Based	C	2b	3	2	Y	N
88267	Washer, Bolt Nut	C	2b	3	2	Y	N
88268	Washer, Bolt, Nut, Non-Spinal, Metallic	C	2b	3	2	Y	N
88269	Wire, Surgical	C	2b	3	U	N	N
88270	Wrench	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
890 PHYSICAL MEDICINE DEVICES							
90001	Accessories, Traction	A	1	1	1	N	N
90002	Accessories, Wheelchair	A	1	1	1	N	N
90003	Adaptor, Dressing	A	1	1	1	N	N
90004	Adaptor, Grooming	A	1	1	1	N	N
90005	Adaptor, Holder, Syringe	A	1	1	1	N	N
90006	Adaptor, Hygiene	A	1	1	1	N	N
90007	Adaptor, Recreational	A	1	1	1	N	N
90008	Adhesive Backed Thermal Skin Patches	A	1	1	1	N	N
90009	Aid, Transfer	A	1	1	1	N	N
90010	Armboard, Wheelchair	A	1	1	1	N	N
90011	Armrest, Wheelchair	A	1	1	1	N	N
90012	Assembly, Knee/Shank/Ankle/Foot, External	A	1	1	2	N	N
90013	Assembly, Shoulder/Elbow/Forearm/Wrist/Hand, Mechanical	A	1	1	U	N	N
90014	Assembly, Shoulder/Elbow/Forearm/Wrist/Hand, Powered	B	2a	2	U	N	N
90015	Assembly, Thigh/Knee/Shank/Ankle/Foot, External	A	1	1	2	N	N
90016	Attachment, Commode, Wheelchair	A	1	1	1	N	N
90017	Attachment, Narrowing, Wheelchair	A	1	1	1	N	N
90018	Band Or Belt, Pelvic Support	A	1	1	1	N	N
90019	Bandage, Cast	A	1	1	1	N	N
90020	Bars, Parallel, Exercise	A	1	1	1	N	N
90021	Bars, Parallel, Powered	A	1	1	1	N	N
90022	Bath, Hydro-Massage	A	1	1	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
890 PHYSICAL MEDICINE DEVICES							
90023	Bath, Paraffin	B	2a	2	2	N	N
90024	Bath, Sitz, Nonpowered	A	1	1	1	N	N
90025	Bath, Sitz, Powered	A	1	1	2	N	N
90026	Bed, Air Fluidized	B	2a	2	2	N	N
90027	Bed, Flotation Therapy, Powered	B	2a	2	2	N	N
90028	Bed, Patient Rotation, Manual	A	1	1	1	N	N
90029	Bed, Patient Rotation, Powered	B	2a	2	2	N	N
90030	Belt, Wheelchair	A	1	1	1	N	N
90031	Blanket, Fire	A	1	1	U	N	N
90032	Board, Lap, Wheelchair	D	3	1	1	N	N
90033	Board, Scooter, Prone	A	1	1	1	N	N
90034	Brake, Extension, Wheelchair	A	1	1	1	N	N
90035	Cabinet, Moist Steam	B	2a	2	2	N	N
90036	Cable	A	1	1	1	N	N
90037	Cable, Electrode	B	2a	2	2	N	N
90038	Chronaximeter	B	2a	2	2	N	N
90039	Cage, Knee	A	1	1	1	N	N
90040	Cane	A	1	1	1	N	N
90041	Cane, Safety Walk	A	1	1	1	N	N
90042	Chair, Adjustable, Mechanical	A	1	1	1	N	N
90043	Chair, Positioning, Electric	A	1	1	2	N	N
90044	Chair, With Casters	A	1	1	1	N	N
90045	Climber, Curb, Wheelchair	A	1	1	1	N	N
90046	Component, External, Limb, Ankle/Foot	A	1	1	1	N	N
90047	Components, Exercise	A	1	1	1	N	N
90048	Components, Wheelchair	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
890 PHYSICAL MEDICINE DEVICES							
90049	Cover, Limb	A	1	1	1	N	N
90050	Crutch	A	1	1	1	N	N
90051	Cuff, Pusher, Wheelchair	A	1	1	1	N	N
90052	Cushion, Flotation	A	1	1	1	N	N
90053	Cushion, Flotation, Therapeutic	A	1	1	U	N	N
90054	Cushion, Wheelchair	A	1	1	1	N	N
90055	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	A	1	1	1	N	N
90056	Device, Finger-Sucking	A	1	2	1	N	N
90057	Device, Fluidized Therapy, Dry Heat	B	2a	2	U	N	N
90058	Device, Iontophoresis, Other Uses	D	3	2	3	N	N
90059	Device, Iontophoresis, Specific Uses	B	2a	2	2	N	N
90060	Device, Muscle Monitoring	B	2a	2	2	N	N
90061	Device, Pressure Applying	A	1	1	1	N	N
90062	Device, Prosthesis Alignment	A	1	1	1	N	N
90063	Device, Warning, Overload, External Limb, Powered	D	3	2	2	N	N
90064	Diathermy, Microwave, For Use In Applying Therapeutic Deep Heat	B	2a	2	2	N	N
90065	Diathermy, Microwave, For Use Other Than Applying Therapeutic Deep Heat	B	2a	2	3	N	N
90066	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat	B	2a	2	2	N	N
90067	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat	C	2b	3	3	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
890 PHYSICAL MEDICINE DEVICES							
90068	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat	B	2a	2	2	N	N
90069	Diathermy, Ultrasonic, For Use Other Than Applying Therapeutic Deep Heat	C	2b	3	3	N	N
90070	Dispenser, Solid Medication	A	1	1	1	N	N
90071	Electrode, Needle, Diagnostic Electromyograph	C	2b	3	2	N	N
90072	Electromyograph, Diagnostic	B	2a	2	2	N	N
90073	Elevator, Wheelchair, Portable	A	1	1	2	N	N
90074	Equipment, Traction, Powered	B	2a	2	2	N	N
90075	Exercise Equipment, Powered, Emg-Triggered	B	2a	2	2	N	N
90076	Exerciser, Finger, Powered	A	1	1	1	N	N
90077	Exerciser, Measuring	B	2a	2	2	N	N
90078	Exerciser, Non-Measuring	A	1	1	1	N	N
90079	Exerciser, Powered	B	3	2	1	N	N
90080	Extracorporeal Shock Wave Treatment	C	2b	3	3	N	N
90081	First Aid Kit With Drug	B	2a	2	N	N	N
90082	Foot Examination Tool For Inflammatory Changes	A	1	1	1	N	N
90083	Footrest, Wheelchair	A	1	1	1	N	N
90084	Garment, Storage, Peritoneal Dialysis Catheter	B	2a	2	1	N	N
90085	Generator, Shock-Wave, For Pain Relief	D	3	2	3	N	N
90086	Hammer, Reflex, Powered	B	2a	2	2	N	N
90087	Hand, External Limb Component, Mechanical	A	1	1	1	N	N
90088	Hand, External Limb Component, Powered	D	3	1	1	N	N
90089	Handrim, Wheelchair	D	3	1	1	N	N
90090	Head Halter, Traction	A	1	1	1	N	N
90091	Helmet, Cranial, For Protective Use	A	1	1	1	N	N

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890 PHYSICAL MEDICINE DEVICES							
90092	Hill Holder, Wheelchair	A	1	1	1	N	N
90093	Holder, Crutch And Cane, Wheelchair	A	1	1	1	N	N
90094	Hook, External Limb Component, Mechanical	A	1	1	1	N	N
90095	Hook, External Limb Component, Powered	A	1	1	1	N	N
90096	Infant Heel Warmer (Chemical Heat Pack)	D	3	1	1	N	N
90097	Insulin Vial Protector/Holder	A	1	1	1	N	N
90098	Joint, Ankle, External Brace	A	1	1	1	N	N
90099	Joint, Elbow, External Limb Component, Mechanical	A	1	1	1	N	N
90100	Joint, Elbow, External Limb Component, Powered	A	1	1	1	N	N
90101	Joint, Hip, External Brace	A	1	1	1	N	N
90102	Joint, Hip, External Limb Component	A	3	1	1	N	N
90103	Joint, Knee, External Brace	A	1	1	1	N	N
90104	Joint, Knee, External Limb Component	A	1	1	1	N	N
90105	Joint, Shoulder, External Limb Component	A	1	1	1	N	N
90106	Lamp, Infrared, Non Heating	B	2a	2	2	N	N
90107	Lamp, Infrared, Therapeutic Heating	B	2a	2	2	N	N
90108	Laser, Comb, Hair	C	2b	3	2	N	N
90109	Light, Lymphedema Reduction, Low Energy	B	2a	2	2	N	N
90110	Manipulator, Plunger-Like Joint	A	1	1	U	N	N
90111	Massager, Powered Inflatable Tube	B	2a	2	2	N	N
90112	Massager, Therapeutic, Electric	A	1	1	1	N	N
90113	Massager, Therapeutic, Manual	A	1	1	1	N	N
90114	Monitor, Orthotic/Prosthetic	A	1	1	1	N	N
90115	Monitor, Spine Curvature	U	U	U	U	N	N
90116	Orthosis, Abdominal	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
890 PHYSICAL MEDICINE DEVICES							
90117	Orthosis, Cervical	A	1	1	1	N	N
90118	Orthosis, Cervical-Thoracic, Rigid	A	1	1	1	N	N
90119	Orthosis, Corrective Shoe	A	1	1	1	N	N
90120	Orthosis, Foot Drop	A	1	1	1	N	N
90121	Orthosis, Limb Brace	A	1	1	1	N	N
90122	Orthosis, Lumbar	A	1	1	1	N	N
90123	Orthosis, Lumbo-Sacral	A	1	1	1	N	N
90124	Orthosis, Moldable, Supportive, Skin Protective	A	1	1	U	N	N
90125	Orthosis, Pneumatic Structure, Rigid	C	2b	3	3	N	N
90126	Orthosis, Rib Fracture, Soft	A	1	1	1	N	N
90127	Orthosis, Sacroiliac, Soft	A	1	1	1	N	N
90128	Orthosis, Thoracic	A	1	1	1	N	N
90129	Orthosis, Truncal, For Dysmenorrhea	A	1	1	1	N	N
90130	Orthosis, Truncal/Orthosis, Limb	A	1	1	1	N	N
90131	Over The Counter Thermal Treatment For Acne.	B	2a	2	2	N	N
90132	Pack, Heat, Moist	A	1	1	1	N	N
90133	Pack, Hot Or Cold, Disposable	A	1	1	1	N	N
90134	Pack, Hot Or Cold, Reuseable	A	1	1	1	N	N
90135	Pack, Hot Or Cold, Water Circulating	A	1	1	2	N	N
90136	Pad, Heating, Powered	B	2a	2	2	N	N
90137	Pad, Medicated, Adhesive, Non-Electric	B	2a	2	U	N	N
90138	Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing	C	2b	3	3	N	N
90139	Platform, Force-Measuring	A	1	1	1	N	N
90140	Plinth	A	1	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
890 PHYSICAL MEDICINE DEVICES							
90141	Powered Laser Non-Thermal Instrument With Non-Heating Effect For Adjunctive Use In Pain Therapy	D	3	2	2	N	N
90142	Powered Light Based Non-Laser Non-Thermal Instrument With Non-Heating Effect For Adjunctive Use In Pain Therapy	B	2a	2	2	N	N
90143	Prosthesis, Thigh Socket, External Component	A	1	1	1	N	N
90144	Pylon, Post Surgical	A	1	1	1	N	N
90145	Refrigerant, Topical (Vapocoolant)	B	2a	2	U	N	N
90146	Reminder, Medication	A	1	1	1	N	N
90147	Restraint, Wheelchair, Non-Protective	A	1	1	1	N	N
90148	Rotator, Transverse	A	1	1	1	N	N
90149	Scale, Platform, Wheelchair	A	1	1	1	N	N
90150	Shoe, Cast	A	1	1	1	N	N
90151	Sling, Arm	A	1	1	1	N	N
90152	Sling, Arm, Overhead Supported	A	1	1	1	N	N
90153	Sling, Overhead Suspension, Wheelchair	A	1	1	1	N	N
90154	Splint, Abduction, Congenital Hip Dislocation	A	1	1	1	N	N
90155	Splint, Clavicle	A	1	1	1	N	N
90156	Splint, Denis Brown	A	1	1	1	N	N
90157	Splint, Hand, And Components	A	1	1	1	N	N
90158	Splint, Temporary Training	A	1	1	1	N	N
90159	Stimulator, Functional Neuromuscular, Scoliosis	B	2a	2	3	N	N
90160	Stimulator, Muscle, Diagnostic	B	2a	2	2	N	N
90161	Stimulator, Muscle, Powered	B	2a	2	2	N	N
90162	Stimulator, Muscle, Powered, Dental	B	2a	2	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
890 PHYSICAL MEDICINE DEVICES							
90163	Stimulator, Muscle, Powered, For Muscle Conditioning	B	2a	2	2	N	N
90164	Stimulator, Muscle, Powered, With Limited Output, For Muscle Conditioning	B	2a	2	2	N	N
90165	Stimulator, Muscle, Powered, With Limited Output, For Rehabilitation	B	2a	2	2	N	N
90166	Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat	B	2a	2	2	N	N
90167	Stimulator, Ultrasound And Muscle, For Use Other Than Applying Therapeutic Deep	B	2a	2	3	N	N
90168	Stirrup, External Brace Component	A	1	1	1	N	N
90169	Stocking, Elastic	A	3	1	1	N	N
90170	Stretcher, Wheeled, Powered	A	3	1	2	N	N
90171	Stroller, Adaptive	A	3	1	1	N	N
90172	Support, Arm	A	3	1	1	N	N
90173	Support, Head And Trunk, Wheelchair	A	3	1	1	N	N
90174	System, Communication, Non-Powered	A	3	1	1	N	N
90175	System, Communication, Powered	A	3	1	2	N	N
90176	System, Environmental Control, Powered	B	3	2	2	N	N
90177	System, Isokinetic Testing And Evaluation	B	3	2	2	N	N
90178	System, Optical Position/Movement Recording	U	3	U	U	N	N
90179	System, Pressure Measurement, Intermittent	A	1	1	1	N	N
90180	Table, Mechanical	A	3	1	1	N	N
90181	Table, Physical Therapy, Multi Function	B	3	2	2	N	N
90182	Table, Powered	A	3	1	1	N	N
90183	Tips And Pads, Cane, Crutch And Walker	A	3	1	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
890 PHYSICAL MEDICINE DEVICES							
90184	Transducer, Miniature Pressure	B	3	2	1	N	N
90185	Transport, Patient, Powered	A	3	1	2	N	N
90186	Treadmill, Mechanical	A	3	1	1	N	N
90187	Treadmill, Powered	D	3	1	1	N	N
90188	Twister, Brace Setting	A	3	1	1	N	N
90189	Unit, Activation, Breath Control	B	3	2	U	N	N
90190	Unit, Chilling	A	3	1	1	N	N
90191	Unit, Fluidotherapy	U	3	U	U	N	N
90192	Unit, Heating, Powered	A	3	1	1	N	N
90193	Unit, Wrist, External Limb Component, Mechanical	A	3	1	1	N	N
90194	Unit, Wrist, External Limb Component, Powered	A	1	1	1	N	N
90195	Utensil, Eating	A	1	1	1	N	N
90196	Utensil, Homemaking	A	1	1	1	N	N
90197	Valve, Prosthesis	B	2a	2	1	N	N
90198	Vehicle, Motorized 3-Wheeled	A	3	1	2	N	N
90199	Vibrator, Therapeutic	A	1	1	1	N	N
90200	Walker, Mechanical	A	1	1	1	N	N
90201	Walker, Mechanical, Poly Vinyl Chloride (Pvc)	A	1	1	1	N	N
90202	Wheelchair, Mechanical	A	1	1	1	N	N
90203	Wheelchair, Powered	A	1	1	2	N	N
90204	Wheelchair, Special Grade	A	1	1	2	N	N
90205	Wheelchair, Stair Climbing	A	1	1	3	N	N
90206	Wheelchair, Standup	A	1	1	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
892 RADIOLOGY DEVICES							
92001	Ablation System, High Intensity Focused Ultrasound (Hifu), Mr-Guided	D	3	4	3	N	N
92002	Accelerator, Linear, Medical	C	2b	3	2	N	N
92003	Accessory - Film Dosimetry System	B	2a	2	2	N	N
92004	Analyzer, Medical Image	C	2b	3	3	N	N
92005	Aperture, Radiographic	B	2a	2	2	N	N
92006	Applicator, Hyperthermia, Deep Heating, Ultrasound	C	2b	3	3	N	N
92007	Applicator, Hyperthermia, Interstitial	C	2b	3	3	N	N
92008	Applicator, Hyperthermia, Superficial, Rf/Microwave	C	2b	3	3	N	N
92009	Apron, Leaded	A	1	1	1	N	N
92010	Apron, Protective	A	1	1	1	N	N
92011	Arthrogram Tray	B	2a	2	2	N	N
92012	Assembly, Tube Housing, X-Ray, Diagnostic	C	2b	3	1	N	N
92013	Assembly, Tube Housing, X-Ray, Therapeutic	C	2b	3	2	N	N
92014	Barrier, Control Panel, X-Ray, Movable	A	1	1	1	N	N
92015	Bed, Scanning, Nuclear	B	2a	2	1	N	N
92016	Betatron, Medical	C	2b	3	2	N	N
92017	Biopsy Needle Guide Kit	B	2a	2	2	N	N
92018	Block, Beam-Shaping, Radiation Therapy	B	2a	2	2	N	N
92020	Cabinet, X-Ray System	B	2a	2	2	N	N
92021	Calibrator, Dose, Radionuclide	B	2a	2	2	N	N
92022	Camera, Focal Spot, Radiographic	B	2a	2	1	N	N
92023	Camera, Multi Format, Radiological	C	2b	3	2	N	N
92024	Camera, Positron	B	2a	2	1	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/ Support
892 RADIOLOGY DEVICES							
92025	Camera, Scintillation (Gamma)	B	2a	2	1	N	N
92026	Camera, X-Ray, Fluorographic, Cine Or Spot	B	2a	2	2	N	N
92027	Cap,Cooling (Infants)	C	2b	3	3	N	N
92028	Cassette, Measurement, Ardran-Crooks	A	1	1	1	N	N
92029	Cassette, Radiographic Film	A	1	1	2	N	N
92030	Chair, Pneumoencephalographic	A	1	1	2	N	N
92031	Changer, Radiographic Film/Cassette	A	1	1	2	N	N
92032	Chest X-Ray Computer Aided Detection	B	2a	2	2	N	N
92033	Coil, Magnetic Resonance, Specialty	D	3	3	2	N	N
92034	Collimator, Automatic, Radiographic	B	2a	2	2	N	N
92035	Collimator, Dermatological, Therapeutic X-Ray	B	2a	2	2	N	N
92036	Collimator, High Voltage, Therapeutic X-Ray	B	2a	2	2	N	N
92037	Collimator, Low Voltage, Therapeutic X-Ray	B	2a	2	2	N	N
92038	Collimator, Manual, Radiographic	B	2a	2	2	N	N
92039	Collimator, Orthovoltage, Therapeutic X-Ray	B	2a	2	2	N	N
92040	Colon Computed Tomography System, Computer Aided Detection	B	2a	2	2	N	N
92041	Cone, Radiographic	B	2a	2	2	N	N
92042	Conformal Brachytherapy Source	C	2b	3	2	N	N
92043	Contrast Media, Ultrasound	C	2b	3	3	N	N
92044	Controller, Temperature, Radiographic	B	2a	2	2	N	N
92045	Couch, Radiation Therapy, Powered	C	2b	3	2	N	N
92046	Counter, Whole Body, Nuclear	B	2a	2	1	N	N
92047	Cradle, Patient, Radiologic	A	1	1	1	N	N
92048	Curtain, Protective, Radiographic	A	1	1	1	N	N
92049	Cyclotron, Medical	C	2b	3	2	N	N

IMDN Number	Medical Device Name	GHTF Risk Class	European Union Risk Class	Canada Risk Class	United States Risk Class	Implant	Life Sustain/Support
892 RADIOLOGY DEVICES							
92050	Densitometer, Bone	C	2b	3	2	N	N
92051	Device, Beam Limiting, Teletherapy, Radionuclide	C	2b	3	2	N	N
92052	Device, Beam Limiting, X-Ray, Diagnostic	B	2a	2	2	N	N
92053	Device, Beam Limiting, X-Ray, Therapeutic	B	2a	2	2	N	N
92054	Device, Communications, Images, Ophthalmic	A	1	1	1	N	N
92055	Device, Digital Image Storage, Radiological	B	2a	2	1	N	N
92056	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System	B	2a	2	2	N	N
92057	Device, Sensing, Optical Contour	B	2a	2	U	N	N
92058	Device, Spot-Film	A	1	1	2	N	N
92059	Device, Storage, Images, Ophthalmic	D	3	1	1	N	N
92061	Diagnostic Ultrasonic Transducer, Robotic	C	2b	3	2	N	N
92062	Digital Breast Tomosynthesis	C	2b	3	3	N	N
92063	Digitizer, Image, Radiological	C	2b	3	2	N	N
92064	Digitizer, Images, Ophthalmic	B	2a	2	2	N	N
92065	Discography Kit	D	3	2	2	N	N
92066	Dosimeter, Ionizing Radiation, Implanted	C	2b	3	2	Y	N
92067	Dryer, Film, Radiographic	A	1	1	2	N	N
92068	Film, Radiographic	A	1	1	1	N	N
92069	Full Field Digital, System, X-Ray, Mammographic	C	2b	3	2	N	N
92070	Generator, Dermatological (Grenz Ray), Therapeutic X-Ray	B	2a	2	2	N	N
92071	Generator, High Voltage, X-Ray, Therapeutic	C	2b	3	2	N	N
92072	Generator, High-Voltage, X-Ray, Diagnostic	C	2b	3	1	N	N
92073	Generator, Low Voltage, Therapeutic X-Ray	C	2b	3	2	N	N

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892 RADIOLOGY DEVICES							
92074	Generator, Orthovoltage, Therapeutic X-Ray	C	2b	3	2	N	N
92075	Generator, Radionuclide	C	2b	3	U	N	N
92076	Grid, Radiographic	A	1	1	1	N	N
92077	High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers	B	2a	2	2	N	N
92078	Holder, Head, Radiographic	A	1	1	1	N	N
92079	Holder, Radiographic Cassette, Wall-Mounted	A	1	1	1	N	N
92080	Holder, Syringe, Lead	A	1	1	1	N	N
92081	Hydrogel Spacer	B	3	2	N	N	N
92082	Hyperthermia System, Bladder Cancer Treatment, With Chemotherapy	C	2b	3	3	N	N
92083	Illuminator, Radiographic-Film	A	1	1	1	N	N
92084	Illuminator, Radiographic-Film, Explosion-Proof	B	2a	2	1	N	N
92085	Image-Intensified Fluoroscopic X-Ray System, Mobile	C	2b	3	2	N	N
92086	Imager, Breast, Electrical Impedance	C	2b	3	3	N	N
92087	Instrument, Quality-Assurance, Radiologic	D	3	2	1	N	N
92088	Interventional Fluoroscopic X-Ray System	C	2b	3	2	N	N
92089	Kit, Barium Enema, Disposable	B	2a	2	U	N	N
92090	Lung Computed Tomography System, Computer-Aided Detection	D	3	2	2	N	N
92091	Magnetic Resonance Imaging Disposable Kit	D	3	2	2	N	N
92092	Media, Reusable Image	B	2a	2	1	N	N
92093	Media,Coupling,Ultrasound	A	1	1	2	N	N
92094	Medium, Contrast, Radiologic	C	2b	3	U	N	N
92095	Microspheres Radionuclide	C	2b	3	3	Y	N

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892 RADIOLOGY DEVICES							
92096	Microtron, Medical	B	2a	2	2	N	N
92097	Monitor, Patient Position, Light-Beam	B	2a	2	1	N	N
92098	Monitor, Ultrasonic, Nonfetal	D	3	3	2	N	N
92099	Needle, Isotope, Gold, Titanium, Platinum	C	2b	3	2	N	N
92100	Needle, Isotope, Reprocessed	C	2b	3	2	N	N
92101	Optical Diagnostic Device For Melanoma Detection	C	2b	3	3	N	N
92102	Phantom, Anthropomorphic, Nuclear	B	2a	2	1	N	N
92103	Phantom, Anthropomorphic, Radiographic	B	2a	2	1	N	N
92104	Phantom, Flood Source, Nuclear	B	3	2	1	N	N
92105	Phantom, Test-Pattern, Radionuclide	B	2a	2	1	N	N
92106	Probe, Uptake, Nuclear	B	2a	2	1	N	N
92107	Processor, Cine Film	B	2a	2	2	N	N
92108	Processor, Radiographic-Film, Automatic	B	2a	2	2	N	N
92109	Processor, Radiographic-Film, Automatic, Dental	B	2a	2	2	N	N
92110	Programmer, Changer, Film/Cassette, Radiographic	A	1	1	2	N	N
92111	Prostate Seeding Kit	B	2a	2	2	N	N
92112	Radiographic Contrast Tray	B	2a	2	2	N	N
92113	Radiographic Protective Glove	A	1	1	1	N	N
92114	Radiology Dental Tray	B	2a	2	2	N	N
92115	Radiology Diagnostic Kit	B	2a	2	2	N	N
92116	Rf/Microwave Hyperthermia System, Cancer Treatment	C	2b	3	f	N	N
92117	Scanner, Fluorescent	B	2a	2	2	N	N
92118	Scanner, Rectilinear, Nuclear	B	2a	2	1	N	N

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892 RADIOLOGY DEVICES							
92119	Scanner, Whole Body, Nuclear	B	2a	2	1	N	N
92120	Screen, Intensifying, Radiographic	A	1	1	1	N	N
92121	Screen, Leaded, Operator Radiation Protector	A	1	1	1	N	N
92122	Seed, Isotope, Gold, Titanium, Platinum	C	2b	3	2	Y	N
92123	Shield, Eye, Radiological	A	1	1	1	N	N
92124	Shield, Gonadal	A	1	1	1	N	N
92125	Shield, Protective, Personnel	A	1	1	1	N	N
92126	Shield, Vial	A	1	1	1	N	N
92127	Solid State X-Ray Imager (Flat Panel/Digital Imager)	B	2a	2	2	N	N
92128	Source, Brachytherapy, Radionuclide	C	2b	3	2	Y	N
92129	Source, Calibration, Sealed, Nuclear	B	2a	2	1	N	N
92130	Source, Isotope, Sealed, Gold, Titanium, Platinum	C	2b	3	2	N	N
92131	Source, Teletherapy, Radionuclide	C	2b	3	1	N	N
92132	Source, Wire, Iridium, Radioactive	C	2b	3	2	N	N
92133	Synchronizer, Ecg/Respirator, Radiographic	B	2a	2	1	N	N
92134	Synchronizer, Electrocardiograph, Nuclear	B	2a	2	1	N	N
92135	Synchrotron, Medical	C	2b	3	2	N	N
92136	System, Applicator, Radionuclide, Manual	B	2a	2	1	N	N
92137	System, Applicator, Radionuclide, Remote-Controlled	C	2b	3	2	N	N
92138	System, Digital Image Communications, Radiological	B	2a	2	1	N	N
92139	System, Hyperthermia, Rf/Microwave (Benign Prostatic Hyperplasia),Thermotherapy	C	2b	3	3	N	N

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892 RADIOLOGY DEVICES							
92140	System, Image Management, Ophthalmic	B	2a	2	2	N	N
92141	System, Image Processing, Radiological	B	2a	2	2	N	N
92142	System, Imaging, Holography, Acoustic	U	U	U	U	N	N
92143	System, Imaging, Optical Coherence Tomography (Oct)	D	3	3	2	N	N
92144	System, Imaging, Pulsed Doppler, Ultrasonic	C	2b	3	2	N	N
92145	System, Imaging, Pulsed Echo, Ultrasonic	C	2b	3	2	N	N
92146	System, Imaging, X-Ray, Electrostatic	C	2b	3	2	N	N
92147	System, Nuclear Magnetic Resonance Imaging	B	2a	2	2	N	N
92148	System, Nuclear Magnetic Resonance Spectroscopic	B	2a	2	2	N	N
92149	System, Radiation Therapy, Charged-Particle, Medical	C	2b	3	2	N	N
92150	System, Radiation Therapy, Neutron, Medical	C	2b	3	2	N	N
92151	System, Radiation Therapy, Radionuclide	C	2b	3	2	N	N
92152	System, Radionuclide Infusion	C	2b	3	U	N	N
92153	System, Rebreathing, Radionuclide	B	2a	2	2	N	N
92155	System, Simulation, Radiation Therapy	C	2b	3	2	N	N
92156	System, Therapeutic, X-Ray	C	2b	3	2	N	N
92157	System, Tomographic, Nuclear	B	2a	2	2	N	N
92158	System, Tomography, Computed, Emission	B	2a	2	2	N	N
92159	System, X-Ray, Angiographic	C	2b	3	2	N	N
92160	System, X-Ray, Film Marking, Radiographic	A	1	1	1	N	N
92161	System, X-Ray, Fluoroscopic, Image-Intensified	C	2b	3	2	N	N
92162	System, X-Ray, Fluoroscopic, Non-Image-Intensified	C	2b	3	2	N	N

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892 RADIOLOGY DEVICES							
92163	System, X-Ray, Mammographic	C	2b	3	2	N	N
92164	System, X-Ray, Mobile	C	2b	3	2	N	N
92165	System, X-Ray, Photofluorographic	C	2b	3	2	N	N
92166	System, X-Ray, Stationary	C	2b	3	2	N	N
92167	System, X-Ray, Tomographic	B	2a	2	2	N	N
92168	System, X-Ray, Tomography, Computed	C	2b	3	2	N	N
92169	System, Planning, Radiation Therapy Treatment	C	2b	3	2	N	N
92170	Table, Radiographic, Non-Tilting, Powered	A	1	1	2	N	N
92171	Table, Radiographic, Stationary Top	A	1	1	2	N	N
92172	Table, Radiographic, Tilting	A	3	1	2	N	N
92173	Table, Radiologic	A	3	1	2	N	N
92174	Tester, Acoustic, Bone Quality	C	3	3	3	N	N
92175	Test-Pattern, Radiographic	A	3	1	1	N	N
92176	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance	C	3	3	2	N	N
92177	Transducer, Ultrasonic, Diagnostic	C	3	3	2	N	N
92178	Transilluminator (Diaphanoscope)	C	3	3	3	N	N
92179	Tube Mount, X-Ray, Diagnostic	C	3	3	1	N	N
92180	Ultrasound, Hyperthermia, Cancer Treatment	C	3	3	3	N	N
92181	X-Ray, Tomography, Computed, Dental	B	3	2	2	N	N

Further Information:

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