

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
4th AMDTC			
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES			
1	Artificial Pancreas Device System, Threshold Suspend	C	
HEMATOLOGY AND PATHOLOGY DEVICES			
2	System, Test, Blood Typing Test	C	Except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1(D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determination which are classified as Class D
IMMUNOLOGY AND MICROBIOLOGY DEVICES			
3	Assay, Genotype, HIV Drug Resistance, In Vitro	C	
4	Enzyme Linked Immunosorbent Assay, T. Cruzi	C	
5	Test, Equipment, Automated Bloodborne Pathogen	A	
CARDIOVASCULAR DEVICES			
6	Barrier, Adhesion, Cardiovascular	D	
7	Cadriovascular Catheter Sheath Introducer Kit	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
8	Catheter, Peripheral, Atherectomy	B	

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9	Clip, Vascular	B	Unless they are long-term surgically invasive medical devices, are in Class C; Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
10	Compressor, Cardiac, External	A	Unless they are active medical device, in which case they are in Class B; Unless they are specifically intended for therapy the vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, in which case they are in Class C
11	Dc-Defibrillator, High Energy, (Including Paddles)	C	Unless they are surgically invasive, in which case they are in Class D
12	Device, Vascular, For Promoting Embolization	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D

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13	Device. Laser Peripheral Angioplasty	B	Unless this is done in a manner that is potentially hazardous with higher power, in which case they are in Class C; Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
14	Endovascular Suturing System	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
15	Fibrillator, Ac	C	Unless they are surgically invasive, in which case they are in Class D
16	Glue,Surgical,Arteries	C	Unless they are absorbable, in which case they are in Class D
17	Graft, Vascular, Synthetic/Biologic Composite	C	Unless they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin are Class D
18	Graft,Vascular,Stainless Steel Tunneler	B	
19	Kit, Balloon Repair, Catheter	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D

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20	Material, Embolization, Neurovascular, Polymerizing Or Precipitating	D	
21	Polymerizing, Neurovascular Embolization Material	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
22	Programmer, Pacemaker	C	
23	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
24	Prosthesis, Vascular Graft, Of Less Than 6mm Diameter	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D

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25	Pulse Generator, External Pacemaker, Dual-Chamber	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
26	Pulse-Generator, Pacemaker, External	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
27	Pulse-Generator, Single Chamber, Single	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
28	Shunt, Portosystemic, Endoprosthesis	C	
29	Stent, Iliac	D	
30	Stent, Renal	C	
31	Stent, Superficial Femoral Artery	C	
32	Suture, Cardiovascular	D	
33	System, Catheter Or Guidewire, Steerable (Magnetic)	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
34	System, Esophageal Pacing	B	

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35	Tissue Graft Of 6mm And Greater	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
36	Tissue Graft Of Less Than 6mm	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
37	Transducer, Pressure, Catheter Tip	B	
38	Transducer, Vessel Occlusion	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
DENTAL DEVICES			
39	Adhesive, Denture, Acacia And Karaya With Sodium Borate > 12% By Weight	A	
40	Adhesive, Denture, Karaya With Sodium Borate	A	

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NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
41	Cord, Retraction	A	
42	Resin, Root Canal Filling Containing Chloroform	B	
EAR, NOSE, AND THROAT DEVICES			
43	Device, Antichoke, Suction	A	Unless they are active medical device, in which case they are in Class B
44	Paste, Injectable For Vocal Cord Augmentation	C	Unless they are absorbable, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
5th AMDTC			
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES			
1	Artificial Pancreas Device System, Bihormonal Control	C	
2	Artificial Pancreas Device System, Single Hormonal Control	C	
IMMUNOLOGY AND MICROBIOLOGY DEVICES			
3	Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus	C	Unless they are intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation, in which case they are in Class D

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NO	PRODUCTS	AMDTC Notes	
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4	Assay,Hybridization And/Or Nucleic Acid Amplification For Detection Of Hepatitis C Rna,Hepatitis C Virus	C	Unless they are intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation, in which case they are in Class D
CARDIOVASCULAR DEVICES			
5	Aid, Cardiopulmonary Resuscitation	B	Unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.
6	Automated External Defibrillators (Non-Wearable)	C	
7	Over-The-Counter Automated External Defibrillator	C	
8	Reprocessed Intravascular Ultrasound Catheter	D	
9	Wearable Automated External Defibrillator	C	
GASTROENTEROLOGY-UROLOGY DEVICES			
10	Agent, Bulking, Injectable For Gastro-Urology Use	C	Unless they are intended to have a biological effect or to be wholly or mainly absorbed, or manufactured from or incorporating animal cells, tissues and/or derivatives thereof, rendered nonviable, cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
11	Analyzer, Diagnostic, Fiber Optic (Colon)	B	

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12	Apparatus, Hemoperfusion, Sorbent	C	
13	Cannula, A-V Shunt	B/C	For short- term use are in Class B, and long-term surgically invasive medical devices, are in Class C
14	Catheter, Hemodialysis, Implanted	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
15	Cooler, Esophageal And Gastric	B	
16	Cooler, Prostatic	B	
17	Device, Ultrasonic, Thermal Ablation	C	
18	Graft, Vascular, Hemodialysis Access, Synthetic/Biological Composite	C/D	For sythetic non absorbable are in Class C, and animal origin absorbable, are in Class D
19	Implant, Anti-Gastroesophageal Reflux	C	
20	Implant, Intragastic For Morbid Obesity	C	
21	Implanted Fecal Incontinence Device	C	
22	Light Source System, Diagnostic Endoscopic	A	
23	Lithotripter, Shockwave (For Treating Gallbladder Stones)	C	
24	Prosthesis, Vas Deferans	C	
25	Replacer, Ureteral	C	
26	Stent, Urethral, Bulbous, Long term	C	
27	Stent, Urethral, Prostatic, Long term	C	
28	Stent, Urethral, Prostatic, Short term	B	
29	Stent,Urethral,External Sphincter, Long Term	C	
30	Transurethral Occlusion Insert, Urinary Incontinence- Control, Female, short term use	B	

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NO	PRODUCTS	AMDTC Notes	
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31	Valve, Ureterovesicle	C	
GENERAL AND PLASTIC SURGERY DEVICES			
32	Bronchial Thermoplasty System	C	
33	Pump, Vacuum, Electric, Suction-Type Electrode	B	
34	Sealant, Polymerizing, Absorbable	D	
35	Surgical Device, For Ablation Of Cardiac Tissue	D	
36	Suture, Absorbable, Natural	D	
37	System, Laser, Photodynamic Therapy, Activation of injected therapeutic compounds or photosensitizing chemical substances for treatment	B	
GENERAL HOSPITAL AND PERSONAL USE DEVICES			
38	Controller, Closed-Loop Blood Glucose	C	
39	Dressing, Wound And Burn, Interactive	B	Unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.
40	Monitor, Skin Resistance/Skin Temperature, For Insulin Reactions	C	
21	Pump, Drug Administration, Closed Loop	C	
NEUROLOGICAL DEVICES			
42	Adhesive, Tissue For Aneurysmorrhaphy	D	
43	Stimulator, Functional Walking Neuromuscular, Non- Invasive	B	
OBSTETRICAL AND GYNECOLOGICAL DEVICES			
44	Band, Tubal Occlusion	D	
45	Barrier, Absorbable, Adhesion	D	

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46	Cap, Cervical, Contraceptive	C	Unless they are incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product (e.g. spermicide), and which is liable to act on the human body with action ancillary to that of the medical devices, are in Class D.
47	Condom, Female, Animal Tissue	D	
48	Condom, Female, Single-Use	C	
49	Device, Occlusion, Tubal, Contraceptive	D	
50	Analyzer, Semen Analysis	B	
51	Device, Thermal Ablation, Endometrial	C	
52	Dilator, Cervical, Expandable	A	Unless they are intended for short-term use , are in Class B
53	Dilator, Cervical, Vibratory	A	Unless they are intended for short-term use , are in Class B
54	Endoscope, Fetal Blood Sampling (And Accessories)	B	
55	Prosthesis, Suture, Cerclage, synthetic, non-absorbable	C	
56	Sensor,Electro-Optical(For Cervical Cancer)	B	
57	Stimulator, Fetal, Acoustic	B	
58	Stimulator, Vaginal, Muscle, Powered, For Therapeutic Use	B	
59	System, Abortion, Metreurynter-Balloon	B	
60	System, Telethermographic, Infrared	B	
61	System, Thermographic, Liquid Crystal, Powered (Adjunctive Use)	B	

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	PHYSICAL MEDICINE DEVICES		
62	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat	B	Unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.
63	Diathermy, Ultrasonic, For Use Other Than Applying Therapeutic Deep Heat	B	Unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.
64	Extracorporeal Shock Wave Treatment, for physical therapy purpose	B	
65	Orthosis, Pneumatic Structure, Rigid	B	
66	Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing	B	