ສາທາລະນະລັດ ປະຊາທິປະໄຕ ປະຊາຊົນລາວ
ສັນຕິພາບ ເອກະລາດ ປະຊາທິປະໄຕ ເອກະພາບ ວັດທະນະຖາວອນ

ກະຊວງສາທາລະນະສຸກ
ກົມອາຫານ ແລະ ຢາ
ໂທ : 021 214 013-4
ແຟັກ: 021 214 015

9606
ເລກທີ /ກອຢ
ນະຄອນຫລວງວຽງຈັນ, ວັນທີ 25 OCT 2023

ໜັງສືແຈ້ງການ

ເຖິງ: ບັນດາບໍລິສັດຂາອອກ-ຂາເຂົ້າດ້ານຢາ ແລະ ຜະລິດຕະພັນການແພດໃນຂອບເຂດທົ່ວປະເທດ.

ເລື່ອງ: ການຈັດຕັ້ງປະຕິບັດຂໍ້ຕົກລົງວ່າດ້ວຍການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດ ສະບັບເລກທີ 1470/ສທ, ລົງວັນທີ 11 ກໍລະກົດ 2023.

- ອີງຕາມ ກົດໝາຍວ່າດ້ວຍຢາ ແລະ ຜະລິດຕະພັນການແພດ ສະບັບເລກທີ 07/ສພຊ, ລົງວັນທີ 21/12/2011;
- ອີງຕາມ ຂໍ້ຕົກລົງຂອງກະຊວງສາທາລະນະສຸກ ວ່າດ້ວຍການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດ ສະບັບເລກທີ 1470/ສທ, ລົງວັນທີ 11 ກໍລະກົດ 2023.

ກົມອາຫານ ແລະ ຢາ, ກະຊວງສາທາລະນະສຸກ ຂໍແຈ້ງມາຍັງບັນດາບໍລິສັດຂາອອກ-ຂາເຂົ້າດ້ານຢາ ແລະ ຜະລິດຕະພັນການແພດໃນຂອບເຂດທົ່ວປະເທດຊາບກ່ຽວກັບ ການຈັດຕັ້ງປະຕິບັດຂໍ້ຕົກລົງຂອງກະຊວງສາທາລະນະສຸກ ວ່າດ້ວຍການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດ ສະບັບເລກທີ 1470/ສທ, ລົງວັນທີ 11 ກໍລະກົດ 2023 ເຊິ່ງໄດ້ກຳນົດແຜນການດັ່ງລຸ່ມນີ້:

1. ໃນເບື້ອງຕົ້ນ ນັບຕັ້ງແຕ່ວັນທີ ວັນທີ 1 ມັງກອນ 2024 ເປັນຕົ້ນໄປ ກົມອາຫານ ແລະ ຢາ ຈະໄດ້ເລີ່ມຈັດຕັ້ງປະຕິບັດການຂຶ້ນທະບຽນອຸປະກອນການແພດ ປະເພດຄວາມສ່ຽງ C ແລະ D, ສຳລັບອຸປະກອນການແພດ ປະເພດຄວາມສ່ຽງ A ແລະ B ຜູ້ປະກອບການຍັງສາມາດດຳເນີນການຂໍອະນຸຍາດນຳເຂົ້າປົກກະຕິ ໂດຍບໍ່ຈຳເປັນຂໍອະນຸຍາດຂຶ້ນທະບຽນ ຫຼື ຈົດແຈ້ງ.
2. ສຳລັບການຈົດແຈ້ງອຸປະກອນການແພດປະເພດຄວາມສ່ຽງ A ແລະ ຂຶ້ນທະບຽນອຸປະກອນການແພດປະເພດຄວາມສ່ຽງ B ແມ່ນຈະເລີ່ມຈັດຕັ້ງປະຕິບັດຕັ້ງແຕ່ວັນທີ 1 ມັງກອນ 2025 ເປັນຕົ້ນໄປ.
3. ເພື່ອກະກຽມການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດຕາມແຜນການໃນຂໍ້ 1 ແລະ 2, ຜູ້ປະກອບການທີ່ດຳເນີນການນຳເຂົ້າ ຫຼື ມີແຜນທີ່ຈະນຳເຂົ້າອຸປະກອນການແພດ, ຈະຕ້ອງນຳສົ່ງບັນຊີລາຍການອຸປະກອນການແພດ ແລະ ປະເພດຄວາມສ່ຽງໂດຍອີງໃສ່ການຂຶ້ນທະບຽນໃນປະເທດຜູ້ຜະລິດ ເຊິ່ງໄດ້ນຳເຂົ້າໃນໄລຍະຜ່ານມາ ຫຼື ມີແຜນການຈະຂໍອະນຸຍາດນຳເຂົ້າໃນຕໍ່ໜ້າ ເຖິງກົມອາຫານ ແລະ ຢາ ກ່ອນວັນທີ 15 ທັນວາ 2023, ເພື່ອເກັບກຳ, ແນະນຳ ແລະ ກະກຽມອຳນວຍຄວາມສະດວກໃນການຂຶ້ນທະບຽນໃຫ້ວ່ອງໄວຕາມກອບເວລາທີ່ໄດ້ກຳນົດໄວ້.
4. ໃນໄລຍະເລີ່ມຕົ້ນ ກໍລະນີທີ່ຜູ້ປະກອບການຍັງບໍ່ສາມາດປະກອບເອກະສານຂໍອະນຸຍາດຂຶ້ນທະບຽນຄົບຖ້ວນຕາມ ASEAN Common Submission Dossier Template (CSDT), ແມ່ນສາມາດປະກອບສະເພາະເອກະສານຂໍ້ 1 ເຖິງ 5 ຕາມມາດຕາ 15 ແລະ ແບບຟອມ ອກ.1 ແລະ ໜັງສືສະເໜີກອບເວລາທີ່ຈະສາມາດສົ່ງເອກະສານຄົບຖ້ວນຕາມ CSDT ເຖິງກົມອາຫານ ແລະ ຢາ.

5. ສຳລັບໂຮງງານຜະລິດພາຍໃນ ທີ່ຈະຂໍອະນຸຍາດຂຶ້ນທະບຽນ ຫຼື ຈົດແຈ້ງອຸປະກອນການແພດ ຕ້ອງດຳເນີນການຈັດປະເພດຄວາມສ່ຽງຂອງອຸປະກອນການແພດຂອງຕົນໂດຍອີງຕາມມາດຕາ 13 ຫຼັກການຈັດປະເພດຄວາມສ່ຽງ ຂອງຂໍ້ຕົກລົງວ່າດ້ວຍການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດ ສະບັບເລກທີ 1470/ສທ.
6. ໃນການຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດທັງຜະລິດພາຍໃນ ແລະ ນຳເຂົ້າ, ພາຍຫຼັງໄດ້ຮັບເອກະສານຄົບຖ້ວນແລ້ວ ໃນຂັ້ນຕອນການປະເມີນດ້ານວິຊາການຂອງກົມອາຫານ ແລະ ຢາ ຈະໄດ້ປະເມີນຄວາມຖືກຕ້ອງຂອງການຈັດປະເພດຄວາມສ່ຽງຂອງຜູ້ປະກອບການໂດຍອີງໃສ່ມາດຕາ 13 ເຊັ່ນດຽວກັນ.
7. ສຳລັບໃນບັນດາປະເທດສະມາຊິກອາຊຽນ, ໃນໄລຍະຜ່ານມາມີການປະຊຸມຮ່ວມກັນ ແລະ ເປັນເອກະພາບໃນການຈັດປະເພດຄວາມສ່ຽງຂອງອຸປະກອນການແພດຈຳນວນໜຶ່ງ (ລາຍລະອຽດຕາມບັນຊີຄັດຕິດ), ແຕ່ການຈັດປະເພດຄວາມສ່ຽງດັ່ງກ່າວແມ່ນບໍ່ແນ່ນອນ ເຊິ່ງອີງໃສ່ການອອກແບບ ແລະ ຈຸດປະສົງການນຳໃຊ້ອຸປະກອນການແພດ ທີ່ໄດ້ກຳນົດໂດຍຜູ້ຜະລິດ ແມ່ນປັດໄຈຫຼັກໃນການຈັດປະເພດຄວາມສ່ຽງຂອງອຸປະກອນການແພດ.
8. ໂດຍອີງຕາມມາດຕາ 13 ສຳລັບອຸປະກອນການແພດທີ່ບໍ່ສາມາດຈັດປະເພດຄວາມສ່ຽງໄດ້ຕາມຫຼັກການຈັດປະເພດຄວາມສ່ຽງ ແມ່ນຖືເອົາການປະເມີນດ້ານວິຊາການ ແລະ ການຕັດສິນຂອງກົມອາຫານ ແລະ ຢາ ໃນການກຳນົດຄວາມສ່ຽງຂອງອຸປະກອນການແພດນັ້ນ, ໃນກໍລະນີອຸປະກອນການແພດທີ່ສາມາດຈັດເປັນຫຼາຍປະເພດຄວາມສ່ຽງ ແມ່ນໃນນັ້ນຈະກຳນົດເອົາຄວາມສ່ຽງສູງສຸດ.
9. ສຳລັບການເກັບຄ່າທຳນຽມຂຶ້ນທະບຽນ ແລະ ຈົດແຈ້ງອຸປະກອນການແພດ ແມ່ນປະຕິບັດຕາມລັດຖະບັນຍັດຂອງປະທານປະເທດ ວ່າດ້ວຍຄ່າທຳນຽມ ແລະ ຄ່າບໍລິການ ເລກທີ 002/ປປທ, ລົງວັນທີ 17 ມິຖຸນາ 2021.

ດັ່ງນັ້ນ, ຈຶ່ງແຈ້ງມາຍັງທ່ານເພື່ອຊາບ ແລະ ປະຕິບັດຕາມແຈ້ງການສະບັບນີ້ດ້ວຍ.

ຫົວໜ້າກົມ

ກະຊວງສາທາລະນະສຸກ ກົມອາຫານ ແລະ ຢາ

ປອ. ດຣ. ບຸນຊູ ແກ້ວຫາວົງ

ສາທາລະນະລັດປະຊາທິປະໄຕປະຊາຊົນລາວ

ສັນຕິພາບເອກະລາດປະຊາທິປະໄຕເອກະພາບວັດທະນະຖາວອນ

ບໍລິສັດ.....

ທີ່ຕັ້ງ.....

ໂທລະສັບ: .....

ໜັງສືສະເໜີ

ຮຽນ: ທ່ານຫົວໜ້າກົມອາຫານ ແລະ ຢາ ທີ່ນັບຖື.

ເລື່ອງ: ນຳສົ່ງບັນຊີລາຍການອຸປະກອນການແພດທີ່ຈະມີການຈໍລະຈອນຈຳໜ່າຍໂດຍບໍລິສັດ.....

- ອີງຕາມ ແຈ້ງການຂອງກົມອາຫານ ແລະ ຢາ ສະບັບເລກທີ.....ລົງວັນທີ.....

ຂ້າພະເຈົ້າ.....ບໍລິສັດ.....ຂໍຖືເປັນກຽດຮຽນສະເໜີມາຍັງທ່ານ ເພື່ອນຳສົ່ງບັນຊີລາຍການອຸປະກອນການແພດທີ່ຈະມີການຈໍລະຈອນຈຳໜ່າຍໂດຍບໍລິສັດລວມທັງໝົດ..... ລາຍການ, ດັ່ງລາຍລະອຽດລຸ່ມນີ້:

ປະເພດຄວາມສ່ຽງ A: .....ລາຍການ

ປະເພດຄວາມສ່ຽງ B:.....ລາຍການ

ປະເພດຄວາມສ່ຽງ C:.....ລາຍການ

ປະເພດຄວາມສ່ຽງ D:.....ລາຍການ

ສຳລັບລາຍການປະເພດຄວາມສ່ຽງ C ແລະ D ຈະສາມາດປະກອບເອກະສານຄົບຖ້ວນຕາມແບບຟອມ ອກ.1 ຂອງກົມອາຫານ ແລະ ຢາ ພາຍໃນ.....(ວັນທີ/ເດືອນ/ປີ).

(ລາຍລະອຽດດັ່ງບັນຊີໄດ້ຄັດຕິດມາພ້ອມນີ້)

ດັ່ງນັ້ນ, ຈຶ່ງຮຽນສະເໜີມາຍັງທ່ານເພື່ອພິຈາລະນາຕາມທາງຄວນດ້ວຍ.

ທີ່ນະຄອນຫຼວງວຽງຈັນ, ວັນທີ.....

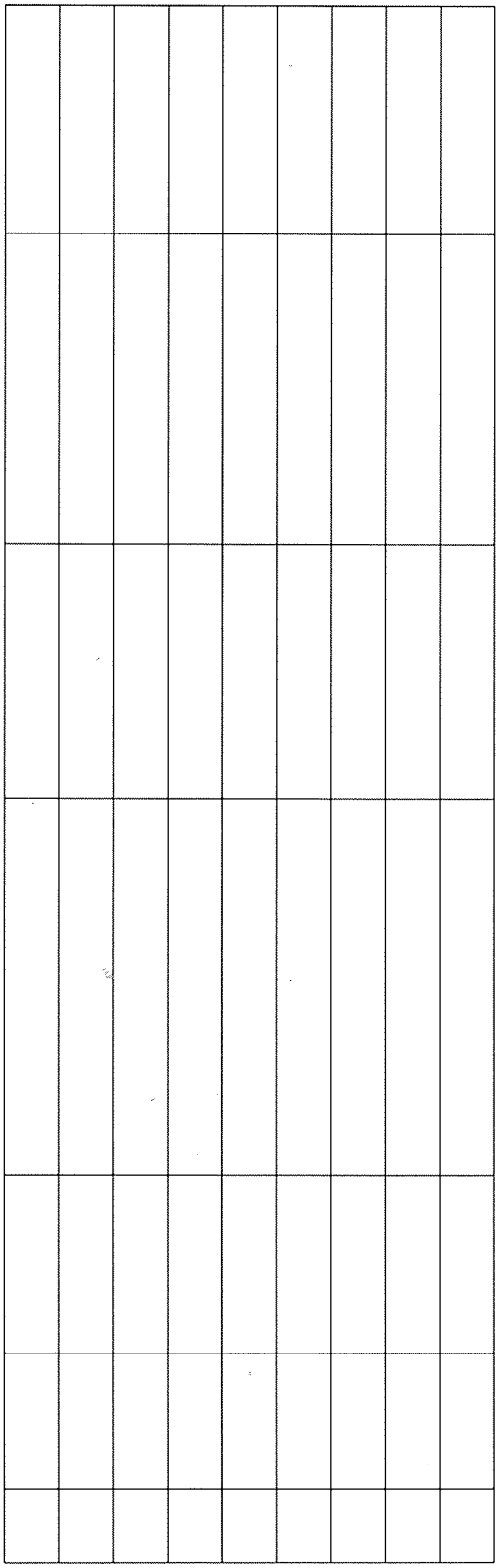
ຜູ້ອຳນວຍການ **ວິຊາການ**

(ລາຍເຊັນ ແລະ ກາຈໍ້າບໍລິສັດ)

ບັນຊີເກັບກຳລາຍການອຸປະກອນການແພດທີ່ນຳເຂົ້າ ແລະ ຈໍລະຈອນຈຳໜ່າຍໃນ ສປປ ລາວ

ຊື່ບໍລິສັດ: .....

ລຳດັບ	ຊື່ຜະລິດຕະພັນ	ຈຸດປະສົງການນຳໃຊ້	ປະເພດຄວາມສ່ຽງທີ່ຖືກຈັດໃນປະເທດຜູ້ຜະລິດ ແລະ ຊື່ປະເທດຜູ້ຜະລິດ	ການນຳເຂົ້າ		ສະຖານະການໄດ້ຮັບມອບສິດໃຫ້ເປັນຕົວແທນຈຳໜ່າຍ		ຜົນການຢັ້ງຢືນຄືນຈາກກົມອາຫານ ແລະ ຢາ ກ່ຽວກັບປະເພດຄວາມສ່ຽງ (ຕື່ມພາຍຫຼັງໂດຍພະແນກທີ່ກ່ຽວຂ້ອງຂອງກົມອາຫານ ແລະ ຢາ)
				ເຄີຍນຳເຂົ້າຜ່ານມາ	ຍັງບໍ່ເຄີຍ (ແຕ່ມີແຜນນຳເຂົ້າ)	ມີ	ບໍ່ມີ	



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	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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 Then 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

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

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

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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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NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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, Intragastric 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	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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, Absorable, Adhesion	D	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
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	

LIST OF HARMONIZED RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	AMDTC Notes	
		CLASS	REMARK
	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	