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MEDICAL DEVICE GUIDANCE DOCUMENT

HARMONISED CLASSIFICATION OF MEDICAL DEVICES IN ASEAN

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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PREFACE

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);
b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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HARMONISED CLASSIFICATION OF MEDICAL DEVICES IN ASEAN

1. Introduction

The ASEAN Medical Device Directive (AMDD) is the Agreement that reflects a legal and institutional framework for the ASEAN Community to harmonise medical devices regulation in the region. It is a common medical device directive in ASEAN among Member States. This Agreement came into force on 1 January 2015. As one of the Member States, Malaysia has signed this Agreement on 23 April 2020.

The classification of medical devices is a requirement under the AMDD, as outlined in Annexes 2 and 3 of Article 4. Under Malaysia's current regulatory framework, the classification system specified in the First Schedule of the Medical Device Regulations 2012 aligns with the AMDD classification. This system categorizes medical devices into four classes (A, B, C, or D) based on a risk-based classification approach. The detailed explanation of the classification is written in this document.

This document aims to guide establishments, particularly manufacturers and authorized representatives, on the risk classification of medical devices, including in-vitro diagnostic (IVD) medical devices, which have been harmonized across ASEAN. This guidance document will be updated annually to incorporate the latest decisions of the ASEAN Medical Device Committee (AMDC).

2. Scope

This guidance document provides the harmonised list of risk classification of medical devices including in-vitro diagnostic (IVD) medical devices based on their intended use/ purpose as claimed by the manufacturer.

This document shall be read in conjunction with the following documents:

a) Medical Device Act 2012 (Act 737); and
b) Medical Device Regulation 2012.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 ASEAN

Association of Southeast Asian Nations, or ASEAN, is a political and economic union of 10 member states in Southeast Asia, which are Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

[Source: asean.org]

3.2 intended use/purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.3 manufacturer

As defined in Section 2 of Act 737.

3.4 medical device

As defined in Section 2 of Act 737.

4. Harmonised Classification of Medical Device in ASEAN

4.1 General Requirements

The risk classification of medical devices listed are harmonised in ASEAN.

The list of harmonised risk classification of identified medical devices are as listed in Annex A.

ANNEX A
(normative)

LIST OF HARMONISED CLASSIFICATION OF MEDICAL DEVICES IN ASEAN

MEDICAL DEVICE NAME	CLASS	REMARK
4th AMDTC		
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
Artificial Pancreas Device System, Threshold Suspend	C	
HEMATOLOGY AND PATHOLOGY DEVICES		
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		
Assay, Genotype, HIV Drug Resistance, In Vitro	C	
Enzyme Linked Immunosorbent Assay, T. Cruzi	C	
Test, Equipment, Automated Bloodborne Pathogen	A	
CARDIOVASCULAR DEVICES		
Barrier, Adhesion, Cardiovascular	D	
Cardiovascular 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.
Catheter, Peripheral, Atherectomy	B	
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.
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.
DC-Defibrillator, High Energy, (Including Paddles)	C	Unless they are surgically invasive, in which case they are in Class D.

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.
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.
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.
Fibrillator, Ac	C	Unless they are surgically invasive, in which case they are in Class D.
Glue,Surgical,Arteries	C	Unless they are absorbable, in which case they are in Class D.
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.
Graft,Vascular,Stainless Steel Tunneler	B	
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.
Material, Embolization, Neurovascular, Polymerizing or Precipitating	D	
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.
Programmer, Pacemaker	C	
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.
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.
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.
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.
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.
Shunt, Portosystemic, Endoprosthesis	C	
Stent, Iliac	D	
Stent, Renal	C	
Stent, Superficial Femoral Artery	C	
Suture, Cardiovascular	D	
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.
System, Esophageal Pacing	B	
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.
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.
Transducer, Pressure, Catheter Tip	B	

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		
Adhesive, Denture, Acacia and Karaya With Sodium Borate > 12% By Weight	A	
Adhesive, Denture, Karaya With Sodium Borate	A	
Cord, Retraction	A	
Resin, Root Canal Filling Containing Chloroform	B	
EAR, NOSE, AND THROAT DEVICES		
Device, Antichoke, Suction	A	Unless they are active medical device, in which case they are in Class B.
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		
Artificial Pancreas Device System, Bihormonal Control	C	
Artificial Pancreas Device System, Single Hormonal Control	C	
IMMUNOLOGY AND MICROBIOLOGY DEVICES		
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.
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		
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.
Automated External Defibrillators (Non-Wearable)	C	

Over-The-Counter Automated External Defibrillator	C	
Reprocessed Intravascular Ultrasound Catheter	D	
Wearable Automated External Defibrillator	C	
GASTROENTEROLOGY-UROLOGY DEVICES		
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.
Analyzer, Diagnostic, Fiber Optic (Colon)	B	
Apparatus, Hemoperfusion, Sorbent	C	
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.
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.
Cooler, Esophageal and Gastric	B	
Cooler, Prostatic	B	
Device, Ultrasonic, Thermal Ablation	C	
Graft, Vascular, Hemodialysis Access, Synthetic/Biological Composite	C/D	For synthetic non-absorbable are in Class C, and animal origin absorbable, are in Class D.
Implant, Anti-Gastroesophageal Reflux	C	
Implant, Intragastric For Morbid Obesity	C	
Implanted Fecal Incontinence Device	C	
Light Source System, Diagnostic Endoscopic	A	
Lithotripter, Shockwave (For Treating Gallbladder Stones)	C	
Prosthesis, Vas Deferans	C	
Replacer, Ureteral	C	
Stent, Urethral, Bulbous, Long term	C	
Stent, Urethral, Prostatic, Long term	C	
Stent, Urethral, Prostatic, Short term	B	
Stent,Urethral,External Sphincter, Long Term	C	
Transurethral Occlusion Insert, Urinary Incontinence- Control, Female, short term use	B	
Valve, Ureterovesicle	C	
GENERAL AND PLASTIC SURGERY DEVICES		
Bronchial Thermoplasty System	C	
Pump, Vacuum, Electric, Suction-Type Electrode	B	

Sealant,Polymerizing, Absorbable	D	
Surgical Device, For Ablation of Cardiac Tissue	D	
Suture, Absorbable, Natural	D	
System, Laser, Photodynamic Therapy, Activation of injected therapeutic compounds or photosensitizing chemical substances for treatment	B	
GENERAL HOSPITAL AND PERSONAL USE DEVICES		
Controller, Closed-Loop Blood Glucose	C	
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.
Monitor, Skin Resistance/Skin Temperature, for Insulin Reactions	C	
Pump, Drug Administration, Closed Loop	C	
NEUROLOGICAL DEVICES		
Adhesive, Tissue for Aneurysmorrhaphy	D	
Stimulator, Functional Walking Neuromuscular, Non- Invasive	B	
OBSTETRICAL AND GYNECOLOGICAL DEVICES		
Band, Tubal Occlusion	D	
Barrier, Absorbable, Adhesion	D	
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.
Condom, Female, Animal Tissue	D	
Condom, Female, Single-Use	C	
Device, Occlusion, Tubal, Contraceptive	D	
Analyzer, Semen Analysis	B	
Device, Thermal Ablation, Endometrial	C	
Dilator, Cervical, Expandable	A	Unless they are intended for short-term use, are in Class B.
Dilator, Cervical, Vibratory	A	Unless they are intended for short-term use, are in Class B.
Endoscope, Fetal Blood Sampling (And Accessories)	B	
Prosthesis, Suture, Cerclage, synthetic, non-absorbable	C	
Sensor,Electro-Optical(For Cervical Cancer)	B	
Stimulator, Fetal, Acoustic	B	
Stimulator, Vaginal, Muscle, Powered, For Therapeutic Use	B	
System, Abortion, Metreurynter-Balloon	B	
System, Telethermographic, Infrared	B	

System, Thermographic, Liquid Crystal, Powered (Adjunctive Use)	B	
PHYSICAL MEDICINE DEVICES		
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.
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.
Extracorporeal Shock Wave Treatment, for physical therapy purpose	B	
Orthosis, Pneumatic Structure, Rigid	B	
Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing	B	
6th AMDTC		
IMMUNOLOGY AND MICROBIOLOGY DEVICES		
Kit, Immunochromatographic, Bacillus Anthracis Differential Antibody	C	
Reagents, 2009 H1n1 Influenza Virus (Swine Origin), Nucleic Acid or Antigen, Detection and Identification	C	
CARDIOVASCULAR DEVICES		
Batteries, Rechargeable	A	
Balloon Aortic Valvuloplasty	D	
Cannula, Arterial, Cardiopulmonary Bypass (CPB), Embolism Protection	D	
Device, Biopsy, Endomyocardial	D	
Probe, Blood-Flow, Extravascular	B	
Pulmonary (Pulmonic) Valvuloplasty Catheters/ Percutaneous Valvuloplasty Catheter	D	
DENTAL DEVICES		
Barrier, Animal Source, Intraoral	D	
Bone Grafting Material, Animal Source	D	
Oral Wound Dressing W/Drug and/or Biologic	D	
Point, Silver, Endodontic	B	
EAR, NOSE, AND THROAT DEVICES		
Collagen, Injectable for Vocal Cord Augmentation	D	
Polymer, Ent Natural-Collagen Material	D	

Replacement, Ossicular (Stapes) Using Absorbable Gelatin Material	D	
GASTROENTEROLOGY-UROLOGY DEVICES		
Catheter, Urinary (Excludes HIV Testing)	B	
GENERAL AND PLASTIC SURGERY DEVICES		
Clamp	A/B	
Composite Cultured Skin (Human Origin)	Non-MD	
Forceps	A/B	
Haemostat Clamp	A/B	
Mesh, Surgical, Absorbable, Abdominal Hernia	D	
NEUROLOGICAL DEVICES		
Catheter, Ventricular, General & Plastic Surgery	D	
7th AMDTC		
RADIOLOGY DEVICES		
Ablation System, High Intensity Focused Ultrasound (Hifu), Mr-Guided	C	
Analyzer,Medical Image, for diagnostic in critical condition	C	
Analyzer,Medical Image, to analyse previously acquired radiology images to identify abnormality during interpretation by the clinician	B	
Applicator, Hyperthermia, Deep Heating, Ultrasound, non-invasive	B/C	Class C if it is High-intensity focused ultrasonic (HIFU) or for high risk application.
Applicator, Hyperthermia, Interstitial, for high risk application	C/D	Class D if they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system.
Applicator, Hyperthermia, Superficial, RF/ Microwave	B/C	Class C if used for high risk application.
Cap,Cooling (Infants), hypothermia therapy in infants to prevent brain damage cause by oxygen deprivation, active device	B	
Digital Breast Tomosynthesis	C	
Hyperthermia System, Bladder Cancer Treatment, with Chemotherapy	C	
Imager, Breast, Electrical Impedance	B	
Optical Diagnostic Device for Melanoma Detection	B	
System, Hyperthermia, Rf/Microwave (Benign Prostatic Hyperplasia), Thermotherapy	C	
Tester, Acoustic, Bone Quality	B	
Transilluminator (Diaphanoscope)	A/B	
Ultrasound, Hyperthermia, Cancer Treatment, non-invasive	C	
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
Automated Urinalysis System	B	

Calculator/Data Processing Module, For Clinical Use, for specific analyte	B/C/D	Follows the risk class of analytes.
Calibrators	B/C/D	Calibrators follows the risk class of reagents or analytes.
Complete Gene Expression Profiling Accessory Reagents	C	
Counter (Beta, Gamma) For Clinical Use	A	
Hyaline Membrane Disease Assay	B/C	
Controls without assigned value	B	
Controls with quantitative or qualitative assigned value	B/C/D	Controls follows the risk class of reagents or analytes.
Real Time Nucleic Acid Amplification System, for specific analyte	B/C/D	Follows the risk class of analytes.
Turbidimetric Method, Globulin test	B	
HEMATOLOGY AND PATHOLOGY DEVICES		
Apparatus, Cell-Freezing and Reagents, for IVD use	A	
Kit, Quality Control for Blood Banking Reagents	C/D	
Manual Blood Grouping and Antibody Test Systems	C/D	
Reagents, Specific, Analyte	B/C/D	
Self-Contained Blood Grouping	C/D	
Substance, Blood Grouping of Non-Human Origin For In Vitro Diagnostic Use	C/D	
System, Test, Automated Blood Grouping and Antibody	C/D	
8th AMDTC		
GENERAL AND PLASTIC SURGERY DEVICES		
Mesh, Surgical, Absorbable, Fistula	D	
Mesh, Surgical, Absorbable, Large Abdominal Wall Defects	D	
Mesh, Surgical, Absorbable, Organ Support	D	
Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement of Tendon	D	
Mesh, Surgical, Absorbable, Plastic and Reconstructive Surgery	D	
Mesh, Surgical, Absorbable, Staple Line Reinforcement	D	
Mesh, Surgical, Absorbable, Thoracic, Chest Wall Reconstruction	D	
Mesh, Surgical, Acetabular, Hip, Prosthesis	C/D	If non-absorbable it will be Class C and Class D if the product is absorbable.
Mesh, Surgical, Collagen, Diaphragmatic Hernia	D	
Mesh, Surgical, Collagen, Fistula	D	
Mesh, Surgical, Collagen, Large Abdominal Wall Defects	D	
Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon	D	

Mesh, Surgical, Collagen, Plastic and Reconstructive Surgery	D	
Mesh, Surgical, Collagen, Plastics, Facial Implants	D	
Mesh, Surgical, Collagen, Staple Line Reinforcement	D	
Mesh, Surgical, Collagen, Thoracic, Chest Wall Reconstruction	D	
Deployment Balloon for Surgical Mesh	B	
Mesh, Surgical, Non-absorbable, For Stress Urinary Incontinence, Male,	C	
Mesh, Surgical, Non-Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Transabdominally Placed	C/D	Class D if the product is from animal origin.
Mesh, Surgical, Non-Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed	C/D	Class D if the product is from animal origin.
Mesh, Surgical, Non-Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator	C/D	Class D if the product is from animal origin.
Mesh, Surgical, Non-absorbable, Polymeric	C	
Septal Stapler/Absorbable Staples	D	
Staple, Non-absorbable, Implantable	C	
Staple, Removable (Skin), for short term	B	
Stapler, Surgical	B	
Suture, Absorbable	D	
Suture, Absorbable, Synthetic	D	
Suture, Absorbable, Synthetic, Polyglycolic Acid	D	
Suture, Knot, Non-absorbable, Mechanical	C	
Suture, Surgical, Absorbable, Polydioxanone	D	
Tape, Surgical, Internal	C/D	
GENERAL HOSPITAL AND PERSONAL USE DEVICES		
Burn Kit include Dressing with Drug	D	
Dressing, Wound and Burn, Hydrogel with Drug and/or Biologic	D	
Dressing, Wound, Collagen	D	
Dressing, Wound, Drug	D	
Gauze, External (With Drug/Biologic/Animal Source Material)	D	
Basic Dressing for external use	A	
NEUROLOGICAL DEVICES		
Balloon,Detachable,For Neurovascular Occlusion	D	
Cannula, Ventricular	D	
Clamp, Carotid Artery, Single Use	B	
Clamp, Carotid Artery, Reusable	A	
Cuff, Nerve	C/D	

Deep Brain Stimulator for Obsessive Compulsive Disorder (OCD)	D	
Instrument, Shunt System Implantation, reusable instrument	A	
Instrument, Shunt System Implantation, single use instrument	B	
Instrument, Shunt System Implantation, if direct contact with Central Nervous System (CNS)	D	
Leukotome	D	
Methyl Methacrylate for Aneurysmorrhaphy	D	
Needle, Neurosurgical Suture	D	
Rongeur, Manual	A/B/D	
Rongeur, Powered	B/D	
Stimulator, Peripheral Nerve, Implanted (Pain Relief)	D	
IMMUNOLOGY AND MICROBIOLOGY DEVICES		
Automated Radioimmunoassay Systems, For Clinical Use include testing agent	B/C/D	
9th AMDTC		
CARDIOVASCULAR DEVICES		
Antimicrobial Blood Pressure Cuff	A	
Blood Pressure Cuff	A	
Bag, Polymeric Mesh, Pacemaker	C/D	Unless they are incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the medical devices, are in Class D
Electrode, Electrocardiograph	A	
Electrode, Electrocardiograph, Multi-Function	A	
Optical Coherence Tomography, Intravascular Catheter	D	
Sizer Heart-Valve Single Use	B	
DENTAL DEVICES		
Cement, Dental	B	
File, Bone, Surgical	A/B	Class A for reusable surgical instrument, Class B for single-use
File, Margin Finishing, Operative	A/B	Class A for reusable surgical instrument, Class B for single-use
File, Periodontic	A/B	Class A for reusable surgical instrument, Class B for single-use
File, Pulp Canal, Endodontic	A/B	Class A for reusable surgical instrument, Class B for single-use
GENERAL HOSPITAL AND PERSONAL USE DEVICES		
Pad, Alcohol, Device Disinfectant	B/C	Class B for general disinfectant and Class C for endpoint sterilisation
Patient Examination Glove	A	
OPHTHALMIC DEVICES		

Apparatus, Cutting, Radiofrequency, Electrosurgical	C	
Catheter, Balloon For Retinal Reattachment	B	
Knife, Ophthalmic	A/B	Class A for reusable surgical instrument, Class B for single-use
Marker, Ocular	A/B	Class B if surgically invasive
Plug, Punctum	B/C/D	Class B if intended for short-term. Class C if intended for long-term. Class D if incorporates material of biological origin
Plug, Scleral, without drug, transient use	B	
Trabeculotome	A/B	Class A for reusable surgical instrument, Class B for single-use
Trephine, Manual, Ophthalmic	A/B	Class A for reusable surgical instrument, Class B for single-use
Weights, Eyelid, External	A	
RADIOLOGY DEVICES		
Needle for radionuclide therapy	A/B/D	Class A for reusable surgical instrument, Class B for single-use. Class D if used in direct contact with the central nervous system.
System, Imaging, Optical Coherence Tomography (Oct)	B	
System, Imaging, Pulsed Doppler, Ultrasonic	B	
System, Imaging, Pulsed Echo, Ultrasonic	B	
System, Nuclear Magnetic Resonance Imaging	B	
System, Tomography, Computed, Emission, non-ionizing radiation	B	
System, X-Ray, Tomographic	C	
Transducer, Ultrasonic, Diagnostic	B/C/D	Class C if used in interventional high-risk procedures. Class D if used in direct contact with the central nervous system
X-Ray, Tomography, Computed, Dental	C	
10th AMDTC		
ANESTHESIOLOGY DEVICES		
Laryngoscope	A/B	Class A if intended for transient use. Class B if intended for short-term use.
Mask, Gas, Anesthetic	B	
Mask, Oxygen	A/B	Class B if connected to active medical device in Class B or higher.
Mask, Oxygen, Low Concentration, Venturi	B	
Mask, Oxygen, Non-Rebreathing	B	
Mask, Scavenging	B	
Mechanical Ventilator	B/C	Class C if this is done in a manner that is potentially hazardous, taking account the nature of the substances involved, the part of the body concerned and the mode and route of administration or removal.
EAR, NOSE, AND THROAT DEVICES		
Balloon, Epistaxis	A	

Hearing Aid, Air Conduction, Transcutaneous System	C	
Hearing Aid, Bone Conduction	C	
Splint, Intranasal Septal (Without drug)	A/D	Class D if incorporates material of biological origin.
Splint, Nasal, External	A	
HEMATOLOGY AND PATHOLOGY DEVICES		
Assay, Fetal Hemoglobin	C	
Assay, Heparin	C	
Assay, Interleukin	B	General purpose assay.
Assay, Sulfhemoglobin	B	
Warmer, Blood, Electromagnetic Radiation	B	
Warmer, Blood, Non-Electromagnetic Radiation	B	
NEUROLOGICAL DEVICES		
Applier, Aneurysm Clip	A/B/D	Class A if reusable. Class B if single-use. Class D if used in direct contact with the central nervous system.
Clip, Scalp, Single Use	B	
Neurological Stereotaxic Instrument	A/B/D	Class A if reusable. Class B if single-use. Class D if used in direct contact with the central nervous system.
Orthopedic Stereotaxic Instrument	A/B	Class A if reusable. Class B if single-use.
Orthosis, Cranial	A	
Stimulator, Low Electric Field, Tumor Treatment	B	
Stimulator, Nerve, Electrical, Percutaneous (Pens), For Pain Relief	B	
ORTHOPEDIC DEVICES		
Bit, Drill	A/B	Class A if reusable. Class B if single-use.
Bone Cement, Antibiotic	D	
Bone, Heterograft	D	
Fastener, Fixation, Biodegradable	D	
Fastener, Fixation, Nondegradable, Soft Tissue	C	
Pin, Fixation, Resorbable, Hard Tissue	D	
Resorbable Spinal Intervertebral Body Fixation Orthosis - Mesh	D	
Resorbable Spinal Intervertebral Body Fixation Orthosis - Plate	D	
Software for Diagnosis/Treatment	B/C	Class C if ● intended to control/monitor the performance of Class C active therapeutic medical devices, or intended directly to influence the performance of such devices, or ● intended for diagnosing in clinical situations where the patient is in immediate danger

Staple, Absorbable	D	
System, External Fixator (With Metallic Invasive Components)	C	
PHYSICAL MEDICINE DEVICES		
Hand, External Limb Component, Mechanical, Non-Powered	A	
Hand, External Limb Component, Powered	A	
Infant Heel Warmer	A	Does not involve conversion of energy
Joint, Elbow, External Limb Component, Non-Powered	A	
Joint, Elbow, External Limb Component, Powered	A	
Joint, Hip, External Limb Component	A	
Joint, Knee, External Limb Component	A	
Joint, Shoulder, External Limb Component	A	
Lamp, Infrared, Therapeutic Heating	B	
11TH AMDC		
CARDIOVASCULAR DEVICES		
Analyzer, Pacemaker Generator Function	C	
Device, Counter-Pulsating, External	B/C	Class C if this is done in a manner that is potentially hazardous, taking account the nature of the treatment involved.
Injector, Indicator	B/C	Class C if this is done in a manner that is potentially hazardous, taking account the nature of the substances involved, the part of the body concerned, and the mode and route of administration or removal.
Introducer, Catheter	B/D	Class D if it diagnoses, monitor or corrects a defect of the heart or of the central circulatory system through direct contact with these parts of the body.
Microsphere, Trace, non-degradable	B/C/D	B if for short-term use. C if for long-term use, or if intended to supply energy in the form of ionising radiation. D if it diagnoses, monitor or corrects a defect of the heart or of the central circulatory system through direct contact with these parts of the body, or an active implantable medical device.
Oximeter	B/C	Class C if intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient or diagnosing in clinical situations where the patient is in immediate danger.
Tourniquet, Automatic Rotating	B	
DENTAL DEVICES		
Absorber, Saliva, Paper	A	
Activator, Ultraviolet, For Polymerization	A	
Agent, Polishing, Abrasive, Oral Cavity	A	
Bar, Performed	A/B	A if for short-term use. B if for long-term use

Bur, Dental	B	
Cephalometer	A	
Dam, Rubber	A	
Device, Anti-snoring	A	
Device, Electric current, Caries Detection	B	
GASTROENTEROLOGY-UROLOGY DEVICES		
Cushion, Hemorrhoid	A	
Desiccator, Transurethral	B	
Dialysate Concentrate for Hemodialysis (Liquid or Powder)	C	
Disinfectant, Dialysate Delivery System	B/C	Class B if used prior to end point sterilisation or higher-level disinfection. Class C if used for sterilizing, or disinfecting as the end point of processing
Disinfectant, Subsystem, Water Purification System for Hemodialysis	C	
Stimulator,Bladder	D	
Endoscopy Capsule or Radio Pill	B	
GENERAL AND PLASTIC SURGERY DEVICES		
Organ bag	B	
Shoe and Shoe Cover, Conductive	A	
Tourniquet, Nonpneumatic	A	
GENERAL HOSPITAL AND PERSONAL USE DEVICES		
Heparin, Vascular Access Flush	D	
Indicator, Physical/Chemical Sterilizer	A	
Injector, Pen (without needle)	A	
Lavage, Jet	B	
Saline, Vascular Access Flush	B	
OPHTHALMIC DEVICES		
Conformer, Ophthalmic, Biological Tissue	D	
Viscoelastic Fluid, Intraocular	B/D	B if for short-term use D if to be wholly or mainly absorbed by the body, or if it incorporates material of biological origin.
Haploscope	B	
Prism, Gonioscopic	A	
Punch, Corneo-Scleral (Reusable)	A	
Sterilizer, Soft-Lens, Thermal, Battery-Powered	C	
Unit, Electrolysis, Battery-Powered, Ophthalmic	B	
12th AMDTC		
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
System, Test, Blood Glucose, Over the Counter	C	
Amikacin Serum Assay	C	
Devices, Breath Trapping, Alcohol	B	
Enzyme Immunoassay, Valproic Acid	C	
Controls for Blood-Gases, (Unassayed)	B	
HEMATOLOGY AND PATHOLOGY DEVICES		

Container, Specimen, Sterile	A	
Activated Whole Blood Clotting Time	C	
System, Fibrinogen Determination	C	
Test, Thrombin Time	C	
Antithrombin III Quantitation	C	
IMMUNOLOGY AND MICROBIOLOGY DEVICES		
Equipment, Rocket Immunoelectrophoresis (for IVD application)	B/C/D	Follows the risk class of analytes
ANESTHESIOLOGY DEVICES		
Absorber, Carbon-Dioxide	B	
Airway, Esophageal (Obturator)	A/B	Class A if intended for Transient Use. Class B if intended for Short-Term Use.
Airway, Nasopharyngeal	A	Class A if intended for Transient and Short-Term Use.
Airway, Oropharyngeal, Anesthesiology	A	Class A if intended for Transient and Short-Term Use.
Catheter, Nasal, Oxygen	B	
CARDIOVASCULAR DEVICE		
Vectorcardiograph	A	
EAR, NOSE, AND THROAT DEVICES		
Otoscope (External)	A	
Blower, Powder, Ent	A	
GASTROENTEROLOGY-UROLOGY DEVICES		
Bag, Bile Collecting	A	
Bag, Urine Collection, Newborn	A	
OPTHALMIC DEVICE		
Adaptometer (Biophotometer), Software-Based Data Acquisition and Stimulus Generation	A	
13th AMDTC		
EAR, NOSE, AND THROAT DEVICES		
Bur, Ear, Nose And Throat, Connected to an electric or pneumatic surgical drill	B	
GASTROENTEROLOGY-UROLOGY DEVICES		
Strip, Dialysate pH Indicator (accessories)	A	
Stimulator, Peripheral Nerve, Non-Implanted, For Pelvic Floor Dysfunction	B	
Stimulator, Electrical, Implantable, For Incontinence	D	
System, Dialysate Delivery, Central Multiple Patient	C	
Endoscopic Contamination Prevention Sheath (for short-term use)	B	
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
5-Amp-Phosphate Release (Colorimetric Test), 5'- Nucleotidase	B	
Bacillus Subtilis, Microbiological Assay, Gentamicin	C	
Fluorescence Polarization Immunoassay, Diphenylhydantoin (Total)	C	
HEMATOLOGY AND PATHOLOGY DEVICES		

Activated Partial Thromboplastin	C	
Automated Digital Image Manual Interpretation Microscope	A	
Chamber, Environmental For The Storage Of Platelet Concentrate	B	
ANESTHESIOLOGY DEVICES		
Bed, Rocking, Breathing Assist	A	
Monitor, Oxygen, Cutaneous, For Uses Other Than For Infant Not Under Gas Anesthesia	B	
Vaporizer, Anesthesia, Non-Heated	C	
CARDIOVASCULAR DEVICES		
Analyzer, Pacemaker Generator Function, Indirect	C	
System, Phonocatheter, Intracavitary (direct contact with the heart)	D	
Pump, Blood, Cardiopulmonary Bypass, Roller Type	C	
NEUROLOGICAL DEVICES		
Guide, Wire, Catheter, Neurovasculature	D	
GENERAL AND PLASTIC SURGERY DEVICES		
Blade, Saw, General & Plastic Surgery, Surgical (electrically-powered)	B	
Gas, Laser Generating	C	
Knife, Surgical	A/B	Class A if reusable. Class B if single-use.
GENERAL HOSPITAL AND PERSONAL USE DEVICES		
Pump, Infusion, Elastomeric	C	
Sterilizer, Chemical (End point sterilisation)	C	
Subcutaneous, implanted, intravascular infusion port and catheter	C	
14th AMDTC		
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
Chromatography for Antibiotic Resistant Bacterial Identification	C	
Thermocycler, Generic	A	
Separator, Automated, Blood cell and Plasma, Sample Preparation	A	
Software, Management, Microplate Assay	A	
IMMUNOLOGY AND MICROBIOLOGY DEVICES		
Kappa, Rhodamine, Antigen, Antiserum	C	
Kit, Identification, Glucose Nonfermenter	B	
Test, Antigen, Nuclear, Epstein-Barr Virus	C	
Trichomonas Vaginalis Nucleic Acid Amplification Test System	C	
EAR, NOSE AND THROAT DEVICES		
Brush, Biopsy, Bronchoscope (Non-Rigid)	A/B	Class A if intended for Transient Use. Class B if intended for Short-Term use or if connected to an active medical device.
Claw, Foreign Body, Bronchoscope (Non-Rigid)	A/B	Class A if intended for Transient Use. Class B if intended for Short-Term use or if connected to an active medical device.

Nasopharyngoscope	B	
Tympanostomy tube	B/C	Class B if intended for Short-Term Use. Cass C if intended for Long-Term Use.
GASTROENTEROLOGY-UROLOGY DEVICES		
Catheter, Biliary, Surgical	B/C	Class B if intended for Short-Term Use. Class C if intended for Long-Term Use
Catheter, Nephrostomy	B/C	Class B if intended for Short-Term Use. Class C if intended for Long-Term Use.
Catheter, Urological	A/B/C	Class A if intended for Transient Use Class B if intended for Short-Term Use. Class C if intended for Long-Term Use.
Endoscope Holder	A	
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES		
5-Fluorouracil Assay	C	
Atomic Absorption, Lithium	C	
Blood and Urine Collection Kit (Excludes HIV Testing)	A	
Dialyzer	C	
Galectin-3 In Vitro Diagnostic Assay (Prognostic)	B	
HEMATOLOGY AND PATHOLOGY DEVICES		
Dialyzer Reprocessing System	C	
Enzyme Linked Immunosorbent Assay, Thrombus Precursor Protein	C	
Kit, Assay, Progesterone Receptor	C	
Kit, Assay, Estrogen Receptor	C	
Red-Cell Count By Photometry	B	
ANESTHESIOLOGY DEVICES		
Anaesthesia conduction needle	B	

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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