Classification of MEDICAL DEVICES

A stethoscope (U.S. FDA product code BZS), a popular Class I medical device as determined by the U.S. FDA, ubiquitous in hospitals.

The regulatory authorities recognize different classes of medical devices based on their potential for harm if misused, design complexity, and their use characteristics. Each country or region defines these categories in different ways. The authorities also recognize that some devices are provided in combination with drugs, and regulation of these combination products takes this factor into consideration.

Classifying medical devices based on their risk is essential for maintaining patient and staff safety while simultaneously facilitating the marketing of medical products. By establishing different risk classifications, lower risk devices, for example, a stethoscope or tongue depressor, are not required to undergo the same level of testing that higher risk devices such as artificial pacemakers undergo. Establishing a hierarchy of risk classification allows regulatory bodies to provide flexibility when reviewing medical devices.

Classification by region

United States

Main article: Medical device manufacturing

Further information: Federal Food, Drug, and Cosmetic Act § Medical devices

Under the Food, Drug, and Cosmetic Act, the U.S. Food and Drug Administration recognizes three classes of medical devices, based on the level of control necessary to assure safety and effectiveness.

- Class I
- Class II
- Class III

Device Class	Risk	FDA Regulatory Control	Examples
Class I	Low Risk	General Controls	Tongue Depressor, Electric Toothbrush, Bandages, Hospital Beds
Class II	Medium Risk	General Controls + Pre-Market Notification (510K)	Catheters, Contact Lenses, Pregnancy Test Kits
Class III	High Risk	General Controls + Special controls (510K) + Pre-Market Approval (PMA)	Pacemakers, Defibrillators, Implanted prosthetics, Breast implants

The classification procedures are described in the Code of Federal Regulations, Title 21, part 860 (usually known as 21 CFR 860).

Class I devices are subject to the least regulatory control and are not intended to help support or sustain life or be substantially important in preventing impairment to human health, and may not present an unreasonable risk of illness or injury. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Class II devices are subject to special labeling requirements, mandatory performance standards and postmarket surveillance. Examples of Class II devices include acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, surgical drapes, stereotaxic navigation systems, and surgical robots.

Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury and require premarket approval. Examples of Class III devices include implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.

European Union (EU) and European Free Trade Association (EFTA)

The classification of medical devices in the European Union is outlined in Article IX of the Council Directive 93/42/EEC and Annex VIII of the EU medical device regulation. There are basically four classes, ranging from low risk to high risk, Classes I, IIa, IIb, and III (this excludes *in vitro* diagnostics including software, which fall in four classes: from A (lowest risk) to D (highest risk)):

Device Class	Risk	Examples
Class I (Class I, Class Is, Class Im, Class Ir)	Low Risk	Tongue Depressor, Wheelchair, Spectacles
Class IIA	Medium Risk	Hearing aids
Class IIB	Medium to High Risk	Ventilators, Infusion pumps
Class III	High Risk	Pacemakers, Defibrillators, Implanted prosthetics, Breast implants

Class I Devices: Non-invasive, everyday devices or equipment. Class I devices are generally low risk and can include bandages, compression hosiery, or walking aids. Such devices require only for the manufacturer to complete a Technical File.

Class Is Devices: Class Is devices are similarly non-invasive devices; however this sub-group extends to include sterile devices. Examples of Class Is devices include stethoscopes, examination gloves, colostomy bags, or oxygen masks. These devices also require a technical file, with the added requirement of an application to a European Notified Body for certification of manufacturing in conjunction with sterility standards.

Class Im Devices: This refers chiefly to similarly low-risk measuring devices. Included in this category are: thermometers, droppers, and non-invasive blood pressure measuring devices.

Once again, the manufacturer must provide a technical file and be certified by a European Notified Body for manufacturing in accordance with metrology regulations.

Class Ir Devices: Reusable surgical instruments include devices like ophthalmic scissors or needle holders. Under the MDR, a manufacturer of Class Ir devices must be certified by a Notified Body with regard to reusability aspects.

Class IIa Devices: Class IIa devices generally constitute low to medium risk and pertain mainly to devices installed within the body in the short term. Class IIa devices are those which are installed within the body for only between 60 minutes and 30 days. Examples include hearing-aids, blood transfusion tubes, and catheters. Requirements include technical files and a conformity test carried out by a European Notified Body.

Class IIb Devices: Slightly more complex than IIa devices, class IIb devices are generally medium to high risk and will often be devices installed within the body for periods of 30 days or longer. Examples include ventilators and intensive care monitoring equipment. Identical compliance route to Class IIa devices with an added requirement of a device type examination by a Notified Body. Note: Some parts of the regulations diffrentiate between Class IIb and Class IIb *implantable* devices, that is, some rules of the MDR apply specifically to Class IIb implantable and Class III devices, e.g. Article 52 paragraph 4 of the MDR.

Class III Devices: Class III devices are strictly high risk devices. Examples include balloon catheters, prosthetic heart valves, pacemakers, etc. The steps to approval here include a full quality assurance system audit, along with examination of both the device's design and the device itself by a European Notified Body.

The authorization of medical devices is guaranteed by a Declaration of Conformity. This declaration is issued by the manufacturer itself, but for products in Class Is, Im, Ir, IIa, IIb or III, it must be verified by a Certificate of Conformity issued by a Notified Body. A Notified Body is a public or private organisation that has been accredited to validate the compliance of the device to the European Directive. Medical devices that pertain to class I (on condition they do not require sterilization or do not measure a function) can be marketed purely by self-certification.

The European classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact, or incorporation of a medicinal product. Certified medical devices should have the CE mark on the packaging, insert leaflets, etc.. These packagings should also show harmonised pictograms and EN standardised logos to indicate essential features such as instructions for use, expiry date, manufacturer, sterile, do not reuse, etc.

In November 2018, the Federal Administrative Court of Switzerland decided that the "Sympto" app, used to analyze a woman's menstrual cycle, was a medical device because it calculates a fertility window for each woman using personal data. The manufacturer, Sympto-Therm Foundation, argued that this was a didactic, not a medical process. the court laid down that an app is a medical device if it is to be used for any of the medical purposes provided by law, and creates or modifies health information by calculations or comparison, providing information about an individual patient.

Japan

Medical devices (excluding in vitro diagnostics) in Japan are classified into four classes based on risk:

Device Class	Risk
Class I	Insignificant
Class II	Low
Class III	High Risk on Malfunction
Class IV	High Risk could cause life-threatening

Classes I and II distinguish between extremely low and low risk devices. Classes III and IV, moderate and high risk respectively, are highly and specially controlled medical devices. In vitro diagnostics have three risk classifications.

Rest of the world

For the remaining regions in the world, the risk classifications are generally similar to the United States, European Union, and Japan or are a variant combining two or more of the three countries' risk classifications.

ASEAN

The *ASEAN Medical Device Directive* (AMDD) has been adopted by several southeast Asian countries. The nations are at varying stages of adopting and implementing the Directive. The AMDD classification is risk-based and defines four levels: A - Low Risk, B - Low to Moderate Risk, C - Moderate – High Risk, and D - High Risk.

Australia

The classification of medical devices in Australia is outlined in section 41BD of the Therapeutic Goods Act 1989 and Regulation 3.2 of the Therapeutic Goods Regulations 2002, under control of the Therapeutic Goods Administration. Similarly to the EU classification, they rank in several categories, by order of increasing risk and associated required level of control. Various rules identify the device's category

Medical device categories in Australia

Classification	Level of risk
Class I	Low
Class I - measuring or Class I - supplied sterile or class IIa	Low - medium
Class IIb	Medium - high

Class III	High
Active implantable medical devices (AIMD)	High

Canada

Spinal boards wait to be used at the York Region EMS logistics headquarters in Ontario

The Medical Devices Bureau of Health Canada recognizes four classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device. Class I devices present the lowest potential risk and do not require a licence. Class II devices require the manufacturer's declaration of device safety and effectiveness, whereas Class III and IV devices present a greater potential risk and are subject to in-depth scrutiny. A guidance document for device classification is published by Health Canada.

Canadian classes of medical devices correspond to the European Council Directive 93/42/EEC (MDD) devices:

- Class I (Canada) generally corresponds to Class I (ECD)
- Class II (Canada) generally corresponds to Class IIa (ECD)
- Class III (Canada) generally corresponds to Class IIb (ECD)
- Class IV (Canada) generally corresponds to Class III (ECD)

Examples include surgical instruments (Class I), contact lenses and ultrasound scanners (Class II), orthopedic implants and hemodialysis machines (Class III), and cardiac pacemakers (Class IV).[34]

India

Medical devices in India are regulated by Central Drugs Standard Control Organisation (CDSCO). Medical devices under the Medical Devices Rules, 2017 are classified as per Global Harmonization Task Force (GHTF) based on associated risks.

The CDSCO classifications of medical devices govern alongside the regulatory approval and registration by the CDSCO is under the DCGI. Every single medical device in India pursues a regulatory framework that depends on the drug guidelines under the Drug and Cosmetics Act (1940) and the Drugs and Cosmetics runs under 1945. CDSCO classification for medical devices has a set of risk classifications for numerous products planned for notification and guidelines as medical devices.[*citation needed*]

Device Class	**Risk**	**Examples**
Class A	Low Risk	Tongue depressors, Wheelchairs, Spectacles, Alcohol Swabs
Class B	Low to Moderate Risk	Hearing aids, Thermometers

Class C	Moderate to High Risk	Ventilators, Infusion pumps
Class D	High Risk	Pacemakers, Defibrillators, Implanted prosthetics, Breast implants

Iran

Iran produces about 2,000 types of medical devices and medical supplies, such as appliances, dental supplies, disposable sterile medical items, laboratory machines, various biomaterials and dental implants. 400 Medical products are produced at the C and D risk class with all of them licensed by the Iranian Health Ministry in terms of safety and performance based on EU-standards.

Some Iranian medical devices are produced according to the European Union standards.

Some producers in Iran export medical devices and supplies which adhere to European Union standards to applicant countries, including 40 Asian and European countries.

Some Iranian producers export their products to foreign countries.

United Kingdom

Following Brexit, the UK medical device regulation was closely aligned with the EU medical device regulation, including classification. The regulation 7 of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), classified general medical devices into four classes of increasing levels of risk: Class I, IIa, IIb or III in accordance with criteria in the UK medical devices regulations, Annex IX (as modified by Schedule 2A to the UK medical devices regulations).