

# Appendix-V

## Medical device

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A **medical device** is a product which is used for medical purposes in patients, in diagnosis, therapy or surgery. If applied to the body, the effect of the medical device is primarily physical, in contrast to pharmaceutical drugs, which exert a biochemical effect. Specific regional definitions of medical device vary slightly as detailed below. The *medical devices* are included in the category *Medical technology*.

Medical devices include a wide range of products varying in complexity and application. Examples include tongue depressors, medical thermometers, blood sugar meters, and X-ray machines.

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## Definitions

### European Union definition

Directive 2007/47/ec of the European Parliament and of the council of 5 September, 2007, which amended the Council Directive 93/42/EEC of 14 June, 1993 concerning medical devices, defines a medical device as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medical devices in the UK under European legislation. Medical devices must not be mistaken with medicinal products. In the EU, all medical devices must be identified with the CE mark.

### **Definition in USA by the Food and Drug Administration**

A medical device, according to the U.S. Food and Drug Administration (FDA), is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

as defined by the Federal Food, Drug, and Cosmetic Act, 21 United States Code [321] (h). Medical devices are regulated by the FDA Center for Devices and Radiological Health (CDRH).

### **Definition in Canada by the Food and Drugs Act**

The term medical devices, as defined in the Food and Drugs Act, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Health Canada reviews medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada.

## **Classification**

The regulatory authorities recognize different classes of medical devices, based on their design complexity, their use characteristics, and their potential for harm if misused. 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.

### **Canada**

The Medical Devices Bureau of Health Canada has recognized 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.<sup>[1]</sup> A guidance document for device classification is published by Health Canada<sup>[2]</sup>.

Canadian classes of medical devices generally correspond to the European Council Directive 93/42/EEC (MDD) devices as follows: Class IV (Canada) generally corresponds to Class III (ECD), Class III (Canada) generally corresponds to Class IIb (ECD), Class II (Canada) generally corresponds to Class IIa (ECD), and Class I (Canada) generally corresponds to Class I (ECD)<sup>[3]</sup>. Examples are surgical instruments (Class I); contact lenses, ultrasound scanners (Class II); orthopedic implants, hemodialysis machines (Class III); and cardiac pacemakers (Class IV)<sup>[4]</sup>.

## United States

The Food and Drug Administration has recognized three classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device.<sup>[1]</sup> The classification procedures are described in the Code of Federal Regulations, Title 21, part 860 (usually known as 21 CFR 860).

### Class I: General Controls

Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. These devices are subject only to general controls. General controls cover such issues as manufacturer *registration* with the FDA, good *manufacturing* techniques, proper *branding* and *labelling*, *notification* of the FDA before marketing the device, and general reporting procedures.<sup>[2]</sup> (Most Class I devices are exempt from the good manufacturing practices and/or the FDA notification regulations.)<sup>[2]</sup> These controls are deemed sufficient to provide reasonable assurance of the safety and effectiveness of the device; or the device is not life-supporting or life-sustaining and does not present a reasonable source of injury through normal usage. Devices in this category include tongue depressors, bedpans, elastic bandages, most hand-held dental instruments, examination gloves, and hand-held surgical instruments and other similar types of common equipment. Depending on the "stated/purported use" of a device, it may be necessary to obtain a Premarket Approval or 510K for the device, which is otherwise classifiable as a Class 1 device. Such devices are referred to as "reserved devices". The electrically powered arthroscope (which is really an endoscope powered electrically) is a case in point. While endoscopes are Class 1 devices, the electrically powered arthroscopes need a pre-market notification (510K) although the manual arthroscopes do not. Pre-market notified devices are marketed as "at least as safe and effective, that is, substantially equivalent, to a legally marketed device."

### Class II: General Controls with Special Controls

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and additional existing methods are available to provide such assurances. Therefore, Class II devices are also subject to special controls in addition to the general controls of Class I devices. Special controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance.<sup>[2]</sup> Devices in Class II are held to a higher level of assurance than Class I devices that they will perform as indicated and will not cause injury or harm to patient or user. Devices in this class are typically non-invasive and include x-ray machines, PACS, powered wheelchairs, infusion pumps, surgical drapes, surgical needles and suture material, acupuncture needles.

### Class III: General Controls and Premarket Approval

A Class III device is one for which insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices. Such a device needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I. Class III devices are described as those for which "insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls ... would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury."<sup>[3]</sup>

Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, implanted cerebral stimulators, implantable pacemaker pulse generators and endosseous (intra-bone) implants (with the exception of root-form endosseous dental implants which were recently reclassified as Class II).

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

The classification of medical devices in the European Union is outlined in Annex IX of the Council Directive 93/42/EEC. There are basically four classes, ranging from low risk to high risk.

- Class I (including Is & Im)
- Class IIa
- Class IIb
- Class III

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, 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 need to be sterilised or are not used to measure a function) can be put on the market purely by self-certification.

The European classification depends on rules that involve the medical device's duration of body contact, its invasive character, its use of an energy source, its effect on the central circulation or nervous system, its diagnostic impact or its 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, don't reuse, etc.

## List of medical devices

### High risk devices

High risk devices are life supports, critical monitoring, energy emitting and other devices whose failure or misuse is reasonably likely to seriously injure patient or staff. Examples include:

- Anesthesia ventilators
- Anesthesia units

- Apnea monitors
- Argon enhanced coagulation units
- Aspirators
- Auto transfusion units
- Invasive Blood pressure units
- Fetal monitors
- Electrosurgical units
- Incubators
- Infusion pump
- Pulse oximeters
- External pacemaker
- Heart Lung Machine

### **Medium risk devices**

These are devices including many diagnostic instruments whose misuse, failure or absence (e.g. out of service) with no replacement available would have a significant impact on patient care, but would not be likely to cause direct serious injury. Examples include:

- ECG
- EEG
- Treadmills
- Ultrasound sensors
- Phototherapy units
- Endoscopes
- Surgical drill and saws
- Laparoscopic insufflators
- Phonocardiographs
- radiant warmers (Adult)
- Zoophagous agents (e.g., medicinal leeches; medicinal maggots)
- Lytic Bacteriophages

### **Low risk devices**

Devices in this category are those whose failure or misuse is unlikely to result in serious consequences. Examples include:

- Electronic thermometer,
- Breast pumps
- Surgical microscope
- Ultrasonic nebulizers
- Sphygmomanometers
- Surgical table
- Surgical lights.
- Temperature monitor
- Aspirators
- X-rays diagnostic equipment

## **Standardization & regulatory concerns**

The ISO standards for medical devices are covered by ICS 11.100.20 and 11.040.01 <sup>[5]</sup>, <sup>[6]</sup>. The quality and risk management regarding the topic for regulatory purposes is convened by ISO 13485 and ISO 14971. Further standards are IEC 60601-1 and for medical software IEC 62304. USFDA also published a series of guidances for industry regarding this topic against 21 CFR Subchapter H—Medical Devices. <sup>[7]</sup>

## Academic resources

- *Medical & Biological Engineering & Computing*
- *Journal of Clinical Engineering* <sup>[8]</sup>

## Industrial resources

- *Journal of Medical Device Regulation*

## Notes & References

1. <sup>^</sup> Department of Justice Canada, "Medical Devices Regulations", SOR/98-282, Feb 21, 2006
2. <sup>^</sup> Heath Canada, Guidance for the Risk-based Classification System
3. <sup>^</sup> Industry Canada, "Canadian Medical Devices Industry"
4. <sup>^</sup> Canadian Agency for Drugs and Technology in Health, "Medical Device Regulation In Canada: A Primer"
5. <sup>^</sup> International Organization for Standardization. "11.100.20: Biological evaluation of medical devices". [http://www.iso.org/iso/products/standards/catalogue\\_ics\\_browse.htm?ICS1=11&ICS2=100&ICS3=20&](http://www.iso.org/iso/products/standards/catalogue_ics_browse.htm?ICS1=11&ICS2=100&ICS3=20&). Retrieved 10 April 2009.
6. <sup>^</sup> International Organization for Standardization. "11.040: Medical equipment". [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_ics/catalogue\\_ics\\_browse.htm?ICS1=11&ICS2=040](http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_ics_browse.htm?ICS1=11&ICS2=040). Retrieved 26 April 2009.
7. <sup>^</sup> USFDA (2009). "Device Publications". <http://www.fda.gov/CbER/dap/devpubs.htm>. Retrieved 26 April 2009.
8. <sup>^</sup> Lippincott Williams & Wilkins. "Journal Information". <http://pt.wkhealth.com/pt/re/jce/home.htm;jsessionid=JpYXfLnQ8TLpH1QhcM0T2HSpsQLFJLTSBcHHmC0QjzGgpPJ9V9Q!-707522149!181195629!8091!-1>. Retrieved 10 April 2009.

1. <sup>^</sup> FDA website: Classify your Medical Device
2. <sup>^</sup> FDA Device Classification
3. <sup>^</sup> Title 21 Food and Drugs Subchapter-H Medical Devices

## See also

- Automated tissue image systems
- Biomedical engineering
- Biomedical equipment technician
- Clinical engineering
- Design history file
- Durable medical equipment
- In vitro diagnostics
- GHTF
- Home medical equipment
- Implant (medicine)
- ISO 13485
- *Journal of Medical Device Regulation*
- List of medical device companies
- Medical device management
  - *Section 201(h)* of Federal Food, Drug, and Cosmetic Act
  - Federal Institute for Drugs and Medical Devices
  - Medical Devices Directive

- U.S. Food and Drug Administration
  - Medical equipment
  - Medical logistics
  - Medical software
  - Pharmacovigilance

## External links

- Device Advice - Is the Product a Medical Device
- 11.040.01: Medical equipment in general - ISO standard series
- US Food and Drug Administration - Center for Devices and Radiological Health
  - Premarket Notification (510k)
  - Premarket Approval (PMA)
- Medical Devices Manufacturers' Association. Medical Devices Manufacturers Association (MDMA)
- EU Commission Medical Devices Homepage
- Surgical Instruments
- UK Medicines and Healthcare products Regulatory Agency: 'How we regulate medical devices'

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