

Definition Medical Devices

Medical Devices refer to any instrument apparatus, appliance, material or other article intended to be used for human beings for the purpose of diagnosis, prevention, monitoring etc. In this section, you also find the distinction of medical devices from in vitro medical devices, medicinal and advanced therapy medicinal products.

Medical Devices

According to the Medical Devices Directive 93/42/EEC (Official Journal L 169) a “medical device” means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings 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,
- and which does 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.

According to the standards of the Global Medical Devices Nomenclature (GMDN), the device categories are

Device category	Examples
Aids for disabled persons	Wheelchair, crutch, standing support, electrical bed, hearing aid
Active and non-active implantable devices	Stent, cardiac pacemaker, hip implant, neurostimulator, insulin pump
Anaesthetic/respiratory equipment	Oxygen mask, anaesthesia breathing circuit, gas delivery unit
Orthopaedic devices	Knee prosthesis, orthopaedic shoe, spinal corset
Dental devices	Dentistry tools and drills, alloys and resins, dental floss, tooth brush
In vitro diagnostics	Devices for clinical chemistry, microbiology, immunology, genetic tests
Ophthalmic devices	Contact lenses, optometre, optical lens, eye glasses, ophthalmoscope
Surgical instruments	Scalpel, surgical drill, forceps, tube, drain, sutures, mask
Biotechnological products	Tissue engineered bone, cartilage and skin
Medical disposables	Bandage, dressing, syringe

Reprocessable medical devices

Medical devices must be labelled by the manufacturer. The label also includes information about whether the medical device is marketed as a single-use or multiple-use device. If the medical device is to be marketed for multiple use, the manufacturer has to also state a method for sterilisation. However, not all medical devices that are “multiple-use” can or should be re-used because functionality or hygienically correct conditions after their reprocessing cannot be guaranteed. Even more perplexing are medical devices that are labelled “single-use” although they can be and are legally reprocessed according to validated procedures that guarantee patient safety is not at risk. However, figures should not be overestimated: a test of 20,000 medical devices by the German reprocessing industry, for instance, revealed that only 16% of all devices labelled as “single use” can be safely reprocessed.

Non-Reprocessable	Reprocessable	
<div data-bbox="245 898 528 1178" style="background-color: #0070C0; color: white; text-align: center; padding: 20px; margin-bottom: 10px;"> <p>Single-Use Devices</p> </div> <p data-bbox="201 1220 555 1346">No safe reprocessing possible Reprocessing should not be allowed</p>	<div data-bbox="654 898 936 1178" style="background-color: #0070C0; color: white; text-align: center; padding: 20px; margin-bottom: 10px;"> <p>Multiple-Use Devices (limited term)</p> </div> <p data-bbox="606 1220 983 1442">Reprocessing possible for times with specific technology (mainly by third party reprocessors) Quality management system and process validation should be obligatory</p>	<div data-bbox="1058 898 1340 1178" style="background-color: #0070C0; color: white; text-align: center; padding: 20px; margin-bottom: 10px;"> <p>Multiple-Use Devices</p> </div> <p data-bbox="1010 1220 1358 1375">Reprocessing poses no major challenges Validated procedures recommended</p>
Labelled as single-use	Labelled as multiple-use	

Distinction of medical devices from similar and related terms

There is often confusion between medical devices and other products of the health care sector:

Distinction from in vitro medical devices

In vitro diagnostic medical devices are a special sub-group of medical devices and pertain to reagents as well as instruments and equipment that is used to examine human tissue or substances for medical purposes. These devices are only used outside the human body to perform medical examinations on samples taken from a patient. They are used to perform research on illnesses such as AIDS or hepatitis, but also to perform glucose or pregnancy tests.

Distinction from medicinal products

A medicinal product is a substance or combination of substances that is administered to the human body. Its aim is to treat or prevent disease in human beings, to make medical diagnosis or to restore, correct or modify physiological functions in the human body.

Distinction from advanced therapy medicinal products

Advanced therapy medicinal products comprise gene therapy products (e.g. a DNA plasmid or human gene to proliferate arterial cells), somatic cell therapy products (e.g. cell lysates to counter renal cancer) and tissue engineered products (e.g. skin substitutes that merge with natural skin to treat venous ulcers and foot skin ulcers). Both gene therapy and somatic cell therapy products (classified as “medicinal products”) are currently regulated under the Medicinal Products Directive (2003/63/EC). A current commission proposal aims at establishing a harmonised EU regulatory framework for human tissue engineered products.

Single-use and multiple-use medical devices

Each medical device has a lifespan of one to several thousand uses. The manufacturers label these medical devices as either single-use or multiple-use.

Single-use medical devices

Contrary to what the word implies, “single-use” does not necessarily define the number of uses that are foreseen for the device. In many countries the labelling does not impede third parties to develop validated procedures which guarantee a safe re-use. If a validated procedure for the reprocessing and re-usability of a medical device has been demonstrated to a notified body, the single-use labelling will be considered as disproved. In these countries, medical devices are labelled as „single-use“ if the original manufacturer does not demonstrate a validated procedure for a specified number of re-uses. The label limits the liability of the producer to the first use. Hereby a „use“ is defined as one medical operation which may include several applications (e.g. surgeries on both eyes).

Multiple-use medical devices

Multiple-use devices are devices which are declared by the manufacture as re-usable. A multi-use product is a product that is designed as a reusable medical device and is correspondingly designed as such. These products can be cleaned and re-sterilized according to the manufacturers' instructions that they are obliged to provide.

Uncritical, semi-critical and critical medical device

In some countries, such as Germany, medical devices fall into so-called risk categories.

- “Non-critical” medical devices include those that are in contact with unbroken skin only (e.g. ECG electrodes). There are no enhanced requirements for reprocessors.
- “Semi-critical” medical devices are those that have been in contact with mucous membranes or pathologically affected skin. Reprocessors have to comply with enhanced requirements (e.g. the use of a special machine).
- “Critical” medical devices comprise those in contact with blood, blood tissue or organs and other sterile medicinal products that permeate the skin or mucous membrane. When reprocessing those medical devices, enhanced requirements can include the special training of personnel or even the certification of the quality management system by a notified body.