



Medical Device

Definition *The term medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used on humans, alone or in combination, for one or more of the following specific medical purposes:*

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or mitigation of diseases,*
- diagnosis, monitoring, treatment, mitigation or compensation of an injury or disability,*
- study, replacement or modification of anatomy or a physiological or pathological process or state,*
- provide information by in vitro examination of samples from the human body, including donated blood and tissue, and which does not exert in or on the human body the principal action for which it is intended by pharmacological, immunological or metabolic means, but whose function may be assisted by such means.*

The following products are also considered medical devices:

- devices to control conception or support conception,*
- products specifically intended for the cleaning, disinfection or sterilisation of the devices referred to in Article 1(4) and those referred to in the first paragraph of this point.*

Under current legislation, certain products that are not intended for medical use are also considered medical devices (ANNEX XVI), such as:

- Contact lenses or other items intended to be placed in or on the eye;*
- Products intended to be introduced wholly or partially into the human body by means of invasive surgical instruments for the purpose of modifying the anatomy or for the fixation of parts of the body with the exception of tattooing and piercing products;*
- Substances, combinations of substances or elements intended for use in facial or other skin or mucosal fillings by subcutaneous, submucosal or intradermal injection, except those for tattoos;*



Glossary

• SITELF •

- *Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;*
- *Equipment that emits high-intensity electromagnetic radiation (e.g. infrared, visible light and ultraviolet) for use on the human body, including coherent and non-coherent, monochromatic and broad-spectrum sources, such as lasers and high-intensity pulsed light equipment for skin photorejuvenation, tattooing or hair removal or other dermal treatment;*
- *Equipment intended for brain stimulation that applies electric currents or magnetic or electromagnetic fields that pass through the skull to modify neuronal activity in the brain.*

Synonyms -

References Ministero della Salute
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Regolamento (UE) 2017/745 e ss.mm.ii.
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