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Increased Scope of „Medical Devices“ and Accessories

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MDD, current

‘medical device’ means 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 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 principle 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.

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‘medical device’ means any instrument, apparatus, appliance, software, **implant, reagent**, material or other article intended by the manufacturer to be used, **alone or in combination**, for human beings **for one or more of the following specific medical purposes**:

- diagnosis, prevention, monitoring, **prediction, prognosis**, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or **disability**,
- investigation, replacement or modification of the anatomy or of a physiological **or pathological process or state**,
- **providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations**,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, **in or on the human body**, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

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

What is an „accessory“ ?



MDD, current

‘accessory’ means

an article which whilst not being a device is intended **specifically** by its manufacturer to be used together **with a device** to enable it to be used in accordance with the use of the device intended by the manufacturer of the device

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‘accessory for a medical device’ means

an article which, whilst not being itself a medical device, is intended by its manufacturer **to be used together with one or several particular medical device(s) to specifically enable the medical device(s)** to be used in accordance with its/their intended purpose(s) **or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)**



4. For the purposes of this Regulation, medical devices, accessories for medical devices, **and products listed in Annex XVI** to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred **to as ‘devices’**.

5. Where justified on account of the similarity between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks, the Commission is **empowered to adopt delegated acts** in accordance with Article 115 to amend the list in Annex XVI, by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects of public health.

3.1. Application of the classification rules shall be governed by the **intended purpose of the devices**.

3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a **product listed in Annex XVI** shall be classified in their own right separately from the device with which they are used.

Article 1 (6) This Regulation does not apply to:




- (f) transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising tissues or cells of **animal origin**, or their derivatives, which are **non-viable** or are rendered non-viable;
- (g) transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of **human origin** which are **non-viable** or are **rendered non-viable**

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)



Contact lenses or other items intended to be introduced into or onto the eye.




Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.




Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.



Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.



High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.



Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.



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