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➔ Question: Are TPP products Medical Devices?

➔ Answers

1. TPP products are no Medical Device (MD), Active Implantable Medical Devices(AIMD) or In Vitro Diagnostic Devices (IVDD) they are for general laboratory use
2. TPP products are invented, manufactured and used for general laboratory use
3. TPP is registered ISO 9001:2015
4. CE marking is not possible
5. Guidelines: "…other tubes, cups, cuvettes or other glass or plastic vessels into which the sample is placed during the analytical process (by aliquot or otherwise) are not considered "sample containers" under the IVDD. They are considered general laboratory equipment. …",

Replacements and Amendments

The rules MDR (EU) 2017/745 (MD/AIMD) and MDR (EU) 2017/746 (IVDD) took their form - to a large extent - from the existing three important directives

1. Medical Devices Directive (MDD) 93/42/EEC
2. Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC
3. In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC

MDR 2017/745 (MD/AIMD)	
REPLACEMENTS	AMMENDMENTS
Medical Devices Directive 93/42/EEC	Community Code Directive 2001/83/EC
Active Implantable Medical Devices Directive 90/385/EEC	Food Safety Regulation (EC) No 178/2002
	Cosmetics Regulation (EC) No 1223/2009

MDR 2017/746 (IVDD)
REPLACEMENTS
In-Vitro Diagnostic Devices Directive 98/79/EC
2 Commission Decision 2010/227/EU

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Regulation (EU) 2017/745

Regulation (EU) 2017/745(MD/AIM) is a regulation of the European Union on the clinical investigation and sale of medical devices for human use. It repeals Directive 93/42/EEC (MDD), which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices, on 26 May 2021.

Regulation (EU) 2017/746

Regulation (EU) 2017/746 (IVDR) is a regulation of the European Union on the placing on the market and putting into service of in vitro diagnostic medical devices (IVD), repealing Directive 98/79/EC (IVDD), which also concerned IVD.

Changes to Directive 93/42/EEC (MDD)

Changes compared to the MDD include changes in device classification and device scope, stricter oversight of manufacturers by Notified Bodies, introduction of the "Person Responsible for Regulatory Compliance" (PRRC) and of the economic operator concept, the requirement of Unique Device Identification (UDI) marking for devices, EUDAMED registration UDI requirements, and increased post-market surveillance activities.

Scope and classification

The scope of the MDR has been expanded to cover a range of products without an intended medical purpose.

➔ Annex XVI of the MDR lists all the respective categories:

! Products for general laboratory use and cell culture are not listed.

ANNEX XVI, List of groups of products without an intended medical purpose

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. 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.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, sub mucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. 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.
6. 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.