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Q: Why do TPP products not have a CE mark?

A: TPP products are intended for general laboratory use and do not fall under the categories of medical devices or IVDs, so CE marking is not required.

Further information on the relevant Regulation (EU) 2017/745

Regulation (EU) 2017/745 is a regulation of the European Union governing the clinical investigation and sale of medical devices for human use. It officially repealed Directive 93/42/EEC (Medical Devices Directive, MDD) and Directive 90/385/EEC (Active Implantable Medical Devices Directive) on 26 May 2021.

Regulation (EU) 2017/745 and other relevant information:

1. PDF version of the regulation:
   https://health.ec.europa.eu/system/files/2020-10/mdr_2017-745_en_0.pdf
2. General guidance and updates:
   https://health.ec.europa.eu/system/files/2020-12/mdr-guidance_0.pdf

Changes to Directive 93/42/EEC (MDD)

Key changes introduced by Regulation (EU) 2017/745 compared to the Medical Device Directive (MDD) include:

- Changes in device classification and scope: Expanded rules and reclassification of certain devices, including stricter criteria for high-risk and borderline products.
- Stricter oversight by Notified Bodies: Enhanced supervision of manufacturers through more rigorous conformity assessments and audits.
- Introduction of the "Person Responsible for Regulatory Compliance" (PRRC): A mandatory role ensuring compliance with regulatory requirements.
- Economic operator concept: Clear responsibilities defined for manufacturers, importers, distributors, and authorized representatives.
- Unique Device Identification (UDI) requirements: Implementation of UDI marking for traceability and enhanced safety monitoring.
- EUDAMED registration: Requirements for registering devices, economic operators, and certificates in the European Database on Medical Devices (EUDAMED).
- Increased post-market surveillance: Stricter obligations for manufacturers to proactively monitor product safety and performance, including periodic safety update reports (PSURs).

Scope and Classification

The scope of Regulation (EU) 2017/745 (MDR) has been expanded to include certain products without an intended medical purpose, as listed in Annex XVI of the regulation. Notably, products for general laboratory use and cell culture are not included in this annex.

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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 modifying anatomy or fixation of body parts, excluding tattooing and piercings.
3. Substances, combinations of substances, or items used for facial or dermal filling via injection or other introduction, excluding tattooing products.
4. Equipment intended to reduce, remove, or destroy adipose tissue, such as devices for liposuction, lipolysis, or lipoplasty.
5. High-intensity electromagnetic radiation equipment (e.g., infra-red, visible light, ultraviolet), including lasers and intense pulsed light devices, for skin resurfacing, tattoo or hair removal, or other treatments.
6. Equipment for brain stimulation using electrical currents, magnetic fields, or electromagnetic fields that penetrate the cranium to modify neuronal activity.