



- **Q: Why do TPP products not have a CE mark?**
→ **A:** TPP products are not medical devices or IVDs; they are invented, manufactured and used for general laboratory purposes.
→ It is not possible to obtain CE marking.

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

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

Changes to Directive 93/42/EEC (MDD)

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

Scope and classification

The scope of the MDR has been expanded to include a number of products without a medical purpose.

- Annex XVI of the MDR lists all relevant 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 articles intended to be placed in or on the eye.
2. Products intended to be introduced, in whole or in part, by surgically invasive means into the human body for altering the anatomy or fixing parts of the body, excluding tattooing products and body piercing.
3. Substances, combinations of substances or articles intended to be used for filling facial or other dermal or mucous membranes by subcutaneous, submucosal or intradermal injection or other introduction, other than for tattooing.
4. Devices intended for the reduction, removal or destruction of adipose tissue, such as liposuction, lipolysis or lipoplasty devices.
5. Equipment emitting high intensity electromagnetic radiation (e.g. infrared, visible light and ultraviolet) intended for use on the human body, including coherent and non-coherent, monochromatic and broadband sources, such as lasers and intense pulsed light devices, for skin resurfacing, tattooing, hair removal or other skin treatment.
6. Brain stimulation devices that apply electrical currents or magnetic or electromagnetic fields that penetrate the skull to modify neuronal activity in the brain.