TPP Techno Plastic Products AG
Zollstrasse 7, CH-8219 Trasadingen, Switzerland
Tel. +41 (0)52 687 01 87, Fax +41 (0)52 687 01 77
info@tpp.ch, www.tpp.ch



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

**A:** TPP products are designed, manufactured, and intended solely for general laboratory use and are not classified as medical devices or in vitro diagnostic devices (IVDs) under Regulation (EU) 2017/745 (MDR) or Regulation (EU) 2017/746 (IVDR).

➔ Therefore, TPP products do not require CE marking.

**Further Information on Regulation (EU) 2017/745 (MDR)**

Regulation (EU) 2017/745, also known as the Medical Device Regulation (MDR), is a European Union regulation governing the clinical investigation, sale, and post-market monitoring of medical devices for human use. It fully replaced Directive 93/42/EEC (MDD) covering medical devices and Directive 90/385/EEC covering active implantable medical devices on May 26, 2021.

**Key Changes from the Medical Devices Directive (93/42/EEC – MDD)**

- **Scope and Classification**: The MDR has expanded the classification and scope of medical devices, introducing new categories and stricter oversight requirements. It now covers certain products without a specific medical purpose, as outlined in Annex XVI.
- **Regulatory Oversight**: The MDR has increased oversight for manufacturers via Notified Bodies, requiring the designation of a Person Responsible for Regulatory Compliance (PRRC) and defining Economic Operators (manufacturers, importers, and distributors) with specific responsibilities.
- **Unique Device Identification (UDI)**: MDR mandates UDI marking to enhance traceability, with devices requiring registration in the European Database on Medical Devices (EUDAMED). While UDI requirements are already in effect, EUDAMED is expected to be fully operational by 2026.
- **Strengthened Post-Market Surveillance**: MDR imposes stricter post-market surveillance and vigilance obligations on manufacturers, with detailed monitoring and reporting processes for device performance and safety.

**Annex XVI: List of Device Categories without a Medical Purpose**

The following product categories, which have no medical purpose, fall under MDR oversight as listed in Annex XVI. General laboratory products and cell culture items are not included in this list:

1. Contact lenses or other articles intended to be placed in or on the eye.
2. Products intended for surgical introduction into the body to alter anatomy or fix body parts (excluding tattooing and body piercing).
3. Substances or articles for dermal filling via injection, excluding tattooing.
4. Devices for adipose tissue reduction or removal, such as liposuction or lipoplasty.
5. High-intensity electromagnetic radiation devices for skin treatment, including lasers and intense pulsed light devices.
6. Brain stimulation devices applying currents or fields to modify brain activity.

**Disclaimer**

TPP products are for research use only and not for clinical, diagnostic or therapeutic use. All products are intended for use by trained personnel that are familiar with safe laboratory practices.

TPP assumes no responsibility for damage or defects resulting from improper or unauthorized use. It is the responsibility of the user to store, handle, and use the products in accordance with the instructions provided.

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