



Regulatory Status of TPP Products (CE-Mark)

1. Intended Use

- TPP products are designed, manufactured, and supplied exclusively for general laboratory use.
- TPP products are not intended for medical, diagnostic, or therapeutic applications.
- TPP products have no claims for clinical, in vitro diagnostic, or human use.

2. Regulatory Classification

TPP products are not a medical device or IVD under:

Regulation (EU) 2017/745 (MDR)

Regulation (EU) 2017/746 (IVDR)

Not subject to MDR/IVDR conformity assessment.

3. CE Marking

TPP products do not carry a CE mark. CE marking is not applicable or possible because products are outside the scope of MDR/IVDR. TPP products should never be interpreted as certified medical devices.

4. Annex XVI MDR Assessment

- TPP products are excluded from Annex XVI categories (products without medical purpose).
 - Examples of Annex XVI categories:
 - Cosmetic contact lenses
 - Devices for body shaping or liposuction
 - Dermal fillers
 - High-intensity lasers/IPL for skin
 - Brain stimulation devices
- ➔ General laboratory consumables and cell culture items such as TPP products are not included.

5. Labeling and Information

- TPP product labeling, Instructions for Use (IFU), sales brochures, website content, and technical documentation (TechDocs) clearly reflect non-medical intended use.
- These materials are reviewed, approved, and controlled under the QMS to prevent any implication of medical, diagnostic, or therapeutic use.



6. Quality Management and Risk Compliance

- TPP products are developed, manufactured, and released under ISO 9001:2015 principles.
- TPP products documented risk management and regulatory assessments ensure continued compliance with intended use and applicable regulatory requirements.
- Any changes to product design, labeling, or intended use are evaluated through a formal change control process.

7. Audit Evidence

Evidence	Description	Reference
Intended Use Statement	Confirms general lab use	QMS / Regulatory Files
Regulatory Assessment	MDR/IVDR applicability review	QMS / Regulatory Files
Annex XVI Review	Documentation of exclusion	QMS / Regulatory Files
CE Mark Statement	Confirmation that CE mark is not applicable	QMS / Product Files
Product Labeling / IFU	Reflects non-medical claims	QMS / Product Files
Risk Management Records	Risk analysis for intended use	QMS / Risk Files

Summary:

TPP products are general laboratory consumables, not medical devices, excluded from MDR/IVDR requirements, and do not and cannot carry a CE mark.

Disclaimer

TPP products are intended for Research Use Only (RUO) and are not approved for clinical, diagnostic, or in vitro fertilization (IVF) applications. The full Terms & Conditions, including limitations of warranty and liability, intended use, and reseller obligations, are available at:

https://www.tpp.ch/page/qualitaets_sicherung/index.php

Distributors who purchase and distribute TPP products acknowledge and agree to these Terms & Conditions and the associated disclaimer.