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

TPP Statement Researche Use Only (RUO)

ISO-Registration

TPP products are manufactured under a Quality Management System (QMS) certified in accordance with ISO 9001:2015, Registration Number 12483, Scope 14. The certification is valid through 14 July 2026 and covers all relevant design, production, and quality assurance processes [1].

Regulatory Status – Research Use Only (RUO)

In accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), TPP Techno Plastic Products AG certifies that its products are intended exclusively for general laboratory use.

All TPP products, including those listed in the TPP sales brochure and on www.tpp.ch, are designated Research Use Only (RUO) [2].

These products:

- Do not meet the definition of an in vitro diagnostic medical device as defined in Article 2 of Regulation (EU) 2017/746.
- Are not intended for diagnostic, screening, monitoring, or medical decision-making purposes.
- Are not intended for use in clinical investigations, patient management, or any medical application.

All TPP products are certified as originating from Switzerland or other EU-approved production sites.

Quality Documentation

For every TPP product, a lot-specific quality certificate can be generated via www.tpp.ch by entering the corresponding product number and lot number. These certificates provide detailed documentation of manufacturing, quality, and compliance parameters for each batch.

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.

Source: [1] https://www.iso.org/standard/62085.html, [2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746