



TPP Sustainability Statement

Quality Management System

TPP operates a documented Quality Management System that is aligned with the principles of ISO 13485 and certified according to ISO 9001. Manufacturing and quality-related activities are performed in accordance with current Good Manufacturing Practice (cGMP) principles, with a focus on product safety, consistency, and traceability.

The effectiveness of the Quality Management System is maintained through documented procedures, risk-based process controls, internal audits, corrective and preventive actions (CAPA), and management review. The ISO 9001 certificate is available at www.tpp.ch.

2. Intended Use and Regulatory Status (RUO Disclaimer)

TPP products are intended for Research Use Only (RUO). They are not intended for use in diagnostic procedures, clinical applications, or therapeutic purposes, and are not classified as in vitro diagnostic (IVD) medical devices.

TPP does not claim compliance with regulatory requirements applicable to clinical, diagnostic, or therapeutic products unless explicitly stated.

4. Product Quality, Sterility, and Hygiene

TPP certifies that all sterile products are manufactured in compliance with approved specifications and validated manufacturing processes. Sterility assurance and product release are based on defined acceptance criteria and documented quality controls.

Personnel involved in manufacturing, packaging, and quality control are trained and required to comply with documented hygiene procedures, contamination control measures, and applicable occupational health and safety regulations.

7. Control of Reuse and Recycling

TPP products are intended for single-use applications. Reuse or recycling of used products is not supported, as current recycling processes cannot be validated to ensure compliance with sterility, purity, material integrity, and performance requirements aligned with ISO 13485 principles.

Identified limitations include:

- Material degradation: Reprocessing may alter polymer properties and compromise product performance.
- Contamination risk: Post-use handling and recycling cannot reliably control biological or chemical contamination.
- Lack of process validation: Recycling processes are not validated to meet applicable product specifications.



8. Environmental and Sustainability Considerations

TPP integrates sustainability considerations into its quality framework while maintaining compliance with safety, performance, and regulatory requirements.

Key measures include:

- Consistent product quality: Reliable performance reduces the need for repeat experiments and unnecessary material consumption.
- Controlled supply chain: Raw materials are sourced within Europe; manufacturing is performed exclusively in Switzerland to minimize transportation impact.
- Packaging efficiency: Modular packaging designs optimize logistics and reduce packaging material usage.
- Energy management: Manufacturing facilities implement energy-efficient technologies, including LED lighting.
- Renewable energy use: Approximately 80% of manufacturing energy is derived from renewable sources.
- Qualified sterilization services: Sterilization is performed by qualified external providers operating under controlled and environmentally responsible conditions.

9. Continuous Improvement and Customer Feedback

TPP maintains a structured continuous improvement process aligned with ISO 13485 principles. Customer feedback, complaints, internal audits, and quality performance data are evaluated within CAPA and management review processes to ensure ongoing compliance, risk control, and process improvement.

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.