



Quality Statement – Correction of USP Chapter Reference 87

TPP Techno Plastic Products AG operates a certified quality management system in accordance with **ISO 9001:2015**. Within this quality management system, manufacturing processes, product specifications, quality controls and relevant documentation are established, controlled and subject to defined review processes.

TPP manufactures its products according to established and controlled manufacturing processes and applicable product specifications. The applicable quality requirements and documentation controls are maintained in accordance with the intended use and applicable requirements for the respective products.

Correction of USP Chapter Reference

In TPP quality certificates, the reference concerning biological safety and cytotoxicity was previously stated incorrectly as USP Chapter 88.

This was identified as a documentation error and corrected on 22 August 2024 to the correct reference, USP Chapter 87.

The correction relates exclusively to the reference stated in the quality documentation. It does not represent a change to the product, its raw materials, manufacturing process, specifications, or quality requirements.

The controlled certificate template and certificate-generation process were updated to ensure that the correct reference is used. Relevant personnel were informed and trained regarding the correction, and the verification of references to applicable standards and pharmacopoeia chapters was reinforced as part of the document review process.

TPP Techno Plastic Products AG confirms that the correction has been implemented in the controlled quality documentation.

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

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