TPP Techno Plastic Products AG
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Quality and Regulatory Statement
TPP Techno Plastic Products AG

Intended Use / Research Use Only (RUO) and IVDR Exclusion

TPP products are intended for Research Use Only (RUO).
The products are not intended for use in in vitro diagnostic procedures, nor for clinical, therapeutic, or medical applications, and are not intended for use in humans or animals. TPP products are not medical devices and are not intended to be used to generate diagnostic results, including patient-specific or patient-related information.
In accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), these products do not fall within the scope of the IVDR, as they are not intended by the manufacturer to be used for diagnostic purposes, disease monitoring, screening, prognosis, prediction, or patient management.
TPP products are not validated, verified, or certified for IVD use, and no performance or safety claims are made for diagnostic or clinical applications. Any use of these products outside their intended RUO purpose is the sole responsibility of the user.

Country of Origin

TPP products are manufactured in Switzerland under ISO 9001:2015 certification and in compliance with current Good Manufacturing Practice (cGMP) guidelines. Quality standards are regularly audited. The ISO certificate can be downloaded at www.tpp.ch.

TPP Techno Plastic Products AG certifies that all sterile products are manufactured in strict accordance with established manufacturing procedures and controlled product specifications. All products meet applicable quality and documentation requirements. Across all TPP facilities, employees adhere to clean handling practices and follow strict hygiene and health protection regulations during production.

ISO Registration

- ISO 9001:2015
- Registration number: 12483
- Scope number: 14

Materials Used

TPP products are manufactured using high-quality, ultra-pure raw materials. No stripping agents or plasticizers (e.g. phthalates), biocides (e.g. DIHEMDA), or lubricants (e.g. oleamides, stearamides, erucamides) are used.

All raw materials comply with the requirements of USP Class VI and relevant medical device material guidelines. TPP products do not contain melamine, silicone, latex, or any animal-derived products or by-products. No latex or animal-based materials are used during the manufacture or packaging of TPP products.

The use of ultra-pure raw materials minimizes the risk of slow leaching of substances from plasticware into buffers and solvents.

Quality Management System Controls

- Deviations

Any deviation from established processes is documented, investigated, and evaluated to determine the root cause and potential impact on product quality. Appropriate Corrective and Preventive Actions (CAPA) are implemented to address identified issues and prevent recurrence. All deviations and CAPA activities are reviewed and approved by the Quality Assurance department to ensure continued compliance with quality and regulatory requirements.

- Change Control System and Communication

TPP operates a structured change control system to ensure that all changes to processes, equipment, materials, or suppliers are evaluated, documented, and approved prior to implementation. TPP distributors are informed of relevant changes through clear and timely communication to maintain transparency, product consistency, and uninterrupted quality.

Quality Control of Incoming Goods and Raw Materials

All incoming goods and raw materials are inspected and tested against predefined specifications. Materials that do not meet requirements are quarantined and managed according to documented procedures to prevent their use in production. Suppliers are regularly evaluated and monitored to ensure continued compliance with quality and performance expectations.

Quality Control and Release of Finished Goods

Finished products undergo comprehensive testing and inspection to confirm compliance with product specifications and applicable quality requirements. Only products that meet all defined acceptance criteria are released for distribution. Quality control records are maintained to ensure full traceability and to support internal and external audits.

Animal Origin / TSE / BSE

No chemicals, additives, or ingredients of animal origin are used in the manufacturing process. TPP products are not exposed to animal-derived materials during storage or transport. All products are free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

Sterilization

TPP performs extensive sterility testing on a routine and/or random basis. Sterility refers to the aseptic condition defined as the absence of viable microorganisms. Each lot of sterile products is certified by TPP.

Product sterility may be compromised if the packaging is damaged or if proper aseptic technique is not followed after opening. Sterilization validation is performed by an independent laboratory in accordance with ISO 11137:2006 guidelines