

## Quality Standards

## Tissue Culture and Laboratory Technology

### Quality Management






TPP is ISO 9001:2008 certified. The ISO quality standard is audited and confirmed by re-certification processes regularly. The certificate can be downloaded at [www.tpp.ch](http://www.tpp.ch).

### Quality Control: from Raw material to the ready TPP Product

TPP provides their end users with the highest quality in tissue culture plastics through the detailed oriented design and manufacturing processes. This intricate monitoring is possible with the complex quality assurance system. Products are dispatched only when all criteria are fulfilled. Therefore TPP guarantees faultless and top-quality products for all areas of tissue culture and laboratory uses.

Raw Material	Production	Maintenance	Quality Control	Dispatch Control
All incoming material and products pass a rigorous and documented quality control based on specifications. Deliveries are accepted from checked vendors only.	Production is in clean room environment on in-line production lines. Regular documented quality controls based on longtime experience and implemented dynamic control plan are performed. Independent laboratories make regular purity and hygiene tests.	For a 24/7 manufacturing process the maintenance and servicing of the molding forms, production lines and infrastructure is extremely important. The accurate planning and execution is basis of the necessary top conditions. Competent specialists arrange daily the availability of the equipment.	All products are tested during and after the manufacturing process based on strict specifications. Each working step can be viewed for years by a sophisticated IT system. Test results and corrective actions are documented.	We perform random examinations of the quality and quantity of the final product with documentation of the results. After release of the data a quality certificate can be generated on <a href="http://www.tpp.ch">www.tpp.ch</a> .

### Standards

	All TPP products are sterilized by radiation. Sterility is maintained as long as the packaging remains unopened and free from visible defect. Factors such as direct sunlight, moisture and large temperature amplitude changes can have negative effects to the sterility. TPP guarantees a "Sterility Assurance Level" (SAL) of $10^{-3}$ .
	Products that are beyond their expiry date (EXP) can cause spurious results or errors. Such products should not be used.
	Each product packaging carries a good visible, black lot number. This batch identification numbers ensures traceability, analyses and monitoring of all data of raw material supply, processes and quality control over a period of several years.
	All TPP products except accessories such as racks etc. are intended for single use only.
	All products are solely intended for general laboratory use by competent staff. The products have not been registered for their direct use on humans.
<b>Zertifikate</b>	Quality certificate from TPP can be generated online at <a href="http://www.tpp.ch">www.tpp.ch</a> .

50 anni in collaborazione con il mondo della sanità, della ricerca scientifica, del controllo ambientale e di qualità

## *Production*

TPP products are manufactured in a clean room environment.

## *Free from pyrogens and detectable endotoxins*

Endotoxins belong to the pyrogens, substances that are eliciting fever. They can influence growth and functionality of tissue cultures. All TPP products are tested systematically with the LAL test to prove the absence of endotoxin. The value of endotoxin is  $< 0.06$  EU/ml with few exceptions. Exact data are available from the quality certificates that can be generated under [www.tpp.ch](http://www.tpp.ch).

## *Free from detectable RNA / DNA*

RNA / DNA are genetic information carriers. Material that is contaminated with RNA / DNA can lead to false positive signals during PCR. They unintentionally amplify along with the desired template. Independent research laboratories periodically test and confirm that no foreign RNA / DNA is detectable with TPP products.

## *Free from detectable RNase / DNase*

RNases / DNases are enzymes that degrade RNA / DNA. They are components of each living cell and cannot be destroyed by the sterilization process. Independent research laboratories periodically test and confirm that no foreign RNase / DNase are detectable with TPP products.

## *Sterility / SAL*

Sterility describes the aseptic condition, i.e. the absence of living organism. During the sterilization process transferable organism such as fungus, bacteria or viruses are killed. TPP receives product sterility through a sterile production processes followed by the gamma sterilization. TPP guarantees a "Sterility Assurance Level" (SAL) by standard products of  $10^{-3}$ , by 3-B products of  $10^{-6}$ . The sterility is validated conforming DIN EN ISO 11137.

## *Growth treatment*

To optimally enhance the adhesion of the cells to the plastic surface, the growth areas of all TPP tissue culture vessels are activated by an optic-mechanic method developed by TPP. The result is a plane and growth enhancing surface that has an optimal proliferation effect. TPP tissue culture products are tested lot wise for their different tissue growth criteria.

## *Free from cytotoxic substances*

Cytotoxic substances are cell poisons that have the ability to weaken or even kill cells. All TPP tissue culture products are free from cytotoxic substances. TPP tests this regularly conforming DIN EN ISO 10993-5.

## *Leaching*

Leaching signifies the slow compounds dissolving (leaching) from plastic ware into buffer and solvents. TPP avoids this by using ultrapure raw-material that is certified to be free of chemical softeners and additive. Recycled raw material never is processed with TPP products. All raw material conforms to the medical directives (93/42) and the Pharmacopoeia USP Class VI. In addition during the production optimized molds that work without any slip agents.