

## CERTIFICATE OF QUALITY

This document certifies that the bellow product meets the following criteria:

TARSONS Catalogue Number:	522100
Substance Name :	Radiation Sterile Racked Graduated Polypropylene Tips 10µl.
Lot Number:	371JSX281021
Date of Manufacture:	October 28, 2021.
Expiration Date:	October 29, 2026, if unopened or undamaged package.

**Quality System Compliance:** Products are manufactured, inspected and found to be in compliance with product and quality specification requirements as documented in the ISO 9001:2015 and ISO 13485:2016 compliant Quality Management System. Inspection records are reviewed and signed for product release.

**Quality control Testing:** Representative production samples are collected and inspected in accordance with current applicable product specifications. Key inspections and inline tests are listed below:

- Visual Inspection – Pass
- Dimensional Inspection – Pass
- Functional Test – Pass

**Raw Material:** Resin is tested, qualified and Heavy metals, Oleamide, diHEMA free.

**DNase/RNase Free:** Products have been tested and are free of any detectable RNase/DNase contamination.

**Non-Pyrogenic:** Tested as per USP BET <85> or EP BET<2.6.14>. Result: less than 0.005EU/Tip.

**Human DNA Free:** Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 5pg.

**Sterilization:** Gamma Sterile according to ISO 11137 <Min Dose 15 kilo Gray>

**BSE/TSE Statement:** The above mentioned product is manufactured without the use of Raw materials of animal origin. Therefore BSE/TSE issue does not concern this product to the best of our knowledge.

**Latex Free Statement:** No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.



SANJIB DEY.  
Quality Assurance Manager.

