

CERTIFICATE OF QUALITY

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

TARSONS Catalogue Number:	522100
Product Name:	Radiation Sterile Racked Graduated Polypropylene Tips 10 μ l.
Lot Number:	698-JSX170323
Date of Manufacture:	March 17, 2023
Expiration Date:	March 16, 2028. if unopened or undamaged package.
Manufactured at:	Unit- IV, TARSONS PRODUCTS LIMITED. Jalan Industrial Complex, Jangalpur, Gate No-1, NH-6, Begri, Howrah- 711411, West Bengal, India.

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 # **TPL-04-MT-001** Key inspections and inline tests are listed below:

Visual Inspection – Pass

Dimensional Inspection – Pass

Functional Test – Pass

Autoclaving: Autoclavable at Temperature = 121°C; Pressure = 15 psi; Time = 20min

Raw Material: Virgin Polypropylene, compliance to FDA 21-CFR.

DNase/RNase Free: Free of detectable DNase 10⁻⁶ Kunitz units & RNase 10⁻⁹ Kunitz units.

Human DNA and PCR Inhibitor Free: Products have been tested and are free of any detectable Human DNA and PCR Inhibitor.

Non-Pyrogenic: Tested as per USP BET <85> or EP BET <2.6.14>.

Result: less than 0.005EU/Tip.

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 DEV. Ph.D.
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Issued on 12th September, 2025