

CERTIFICATE OF QUALITY

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

TARSONS Catalogue Number:	522103
Substance Name :	Radiation Sterile Racked Graduated Polypropylene Tips 1000 μ l.
Lot Number:	485JS-151222
Date of Manufacture:	December 15, 2022.
Expiration Date:	December 14, 2027, if unopened or undamaged package.
Manufactured at:	Unit- IV, Jalan Industrial Complex, Jangalpur, Gate No-1, Biprannapara, Howrah– 711411, 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. 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, diHEMDA 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.

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.
Sr. Manager, Quality Assurance.

