

Certificate of product line quality

Automation Disposable Tips product family

Thermo Fisher Scientific, Inc. certifies that the Automation Disposable Tips product family has been manufactured in accordance with established manufacturing guidelines and product specifications. These products are subject to rigorous quality inspections and are proven to conform to the highest internally established quality requirements and external standards as applicable. The following quality control criteria apply to the aforementioned product family:



Item	Description	Certified quality	Sterile	PCR ready	Sterile & PCR ready
Non-regulated product	Based on the Intended Use and/or Indicates for Use, this product family is not considered to be a medical device.	■	■	■	■
Materials	All products are produced with materials such as virgin polypropylene. No recycled materials are used in the manufacture of these products. Our material suppliers do not use or intentionally incorporate the following agents into the materials used for production: Plasticizers (softeners/phthalates), Melamine, Silicone, or Latex. NOTE: This information only applies to disposable tips	■	■	■	■
Filter Tip	A filter within the disposable tip that serves to prevent aerosol contamination when pipetting.			■	■
Production	Products are manufactured in a controlled environment.	■	■	■	■
Functional testing	Products undergo continuous quality controls regarding product function; this includes dimensional checks, leak testing, %CV testing, tip straightness check, and visual defect inspection.	■	■	■	■
Sterility	Sterile products are sterilized by electron beam irradiation according to ISO 11137; 10 ⁻⁶ Sterility Assurance Level (SAL); has a shelf life of 5 years.		■		■
Sterilization Dose Audit	Audited quarterly according to ISO 11137.		■		■
Endotoxin-free	An extract from the lot was tested and certified non-endotoxic with a documented endotoxin level of less than 0.06 EU/ml in conformance with the Limulus Amebocyte Lysate (LAL) test method per USP < 85 >.	■	■	■	■
Animal components	All resins, colorants, and components used in the manufacture of the product contain no animal-derived ingredients or comply with the latest revision of EMA/410/01 section 6.4.	■	■	■	■

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Automation Disposable Tips product family (continued)



Item	Description	Certified quality	Sterile	PCR ready	Sterile & PCR ready
Bisphenol A (BPA) free	BPA has not been used in the manufacturing process of the plastic in question.	■	■	■	■
Adenosine triphosphate (ATP) free	Products are tested for the presence of ATP using a bioluminescence luciferase assay. Products with ATP levels below the experimental baseline value are certified ATP-free in the range <math> < 10^{-13} \text{ mg}/\mu\text{l}</math>. NOTE: This information only applies to disposable tips.	■	■	■	■
Polymerase chain reaction (PCR) Inhibitors	This product is certified to be free of PCR Inhibitors to <math> < 0.1 \text{ pg}</math> by amplification of a human DNA target sequence. PCR is performed including the appropriate controls and all reactions are analyzed by gel electrophoresis. Test and control reactions must amplify the expected DNA fragment with equivalent yield and purity to verify that the product is free of detectable PCR inhibitors.	■	■	■	■
Nucleases	This product is certified to be free of detectable Ribonuclease (RNase) / Deoxyribonuclease (DNase) contamination. This test is performed using the nuclease assay method with a detection limit of 1.9×10^{-10} Kunitz unit/μl for RNase and 8×10^{-7} Kunitz unit/μl for DNase.	■	■	■	■
DNA	Products undergo continuous quality controls regarding product function; this includes dimensional checks, leak testing, %CV testing, tip straightness check, and visual defect inspection.	■	■	■	■

Available in Fit for Purpose



ISO 9001
Certified

ISO 14001
Certified

ISO 13485
Certified

Thermo Fisher Scientific, Inc. Quality Management System is certified in accordance with international Quality Management standards. All sites are certified to one or more Quality Management standards; refer to the [Site ISO Certifications](#) for copies of relevant ISO Certifications.

Changes to manufacturing procedures, packaging, and product specifications are documented and traceable.

All products are fully traceable by lot number. For a lot-specific certificate, please visit us at thermofisher.com.

For any additional information or inquires, Contact Us for Support ([Link](#)) and choose the appropriate option.

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Laboratory Products Division

Learn more at thermofisher.com/fitforpurpose

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