

# Certificate of product line quality

## ClipTip Pipette Tips product family

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



Item	Description	PCR ready	Sterile & PCR ready	Forensic ready
<b>Laboratory use, non-regulated</b>	Based on the Intended Use and/or Indicates for Use, this product family is not considered to be a medical device.	■	■	■
<b>Materials</b>	Products are produced from virgin resins and are absent of recycled resins. All products are produced with materials such as polypropylene compound (Low Retention additive) and polyethylene (filter). Our material suppliers do not use or intentionally incorporate the following agents into the materials used for production: plasticizers (softeners/phthalates), or latex.	■	■	■
<b>Production</b>	Products are manufactured in a controlled environment.	■	■	■
<b>Functional testing</b>	Products undergo continuous quality controls regarding product function; this includes functional testing with the instrument (sample-based).	■	■	■
<b>Sterility</b>	Sterile products are sterilized by irradiation according to ISO 11137; 10 <sup>-6</sup> Sterility Assurance Level (SAL); has an expiry date of 5 years from manufacturing date.		■	■
<b>Sterilization Dose Audit</b>	Audited according to ISO 11137.		■	■
<b>Non-endotoxin</b>	Certified non-endotoxin with an endotoxin level of less than 0.06 EU/ml in conformance with the Limulus Amebocyte Lysate (LAL) test method per USP < 85 >.	■	■	■
<b>Animal components</b>	Tallow-derived materials used in the product fulfil the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the “Note for Guidance EMA/410/01, and as amended.	■	■	■
<b>Bisphenol A (BPA) free</b>	BPA has not been used in the manufacturing process of the plastic in question.	■	■	■
<b>Adenosine triphosphate (ATP) free</b>	Products are tested for the presence of ATP using a luciferase-based detection assay. Products with ATP levels below the experimental baseline value of 10 <sup>-13</sup> are certified ATP-free.	■	■	■

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## ClipTip Pipette Tips product family (continued)



Item	Description	PCR ready	Sterile & PCR ready	Forensic ready
<b>Polymerase chain reaction (PCR) Inhibitors</b>	Tips are tested for the presence of PCR inhibitors by amplification of a human and mouse 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 amplicons with equivalent yield and purity to verify that the tips are free of detectable PCR inhibitors.	■	■	■
<b>Nucleases</b>	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 10 <sup>-9</sup> Kunitz unit/μl for RNase and 10 <sup>-7</sup> Kunitz unit/μl for DNase.	■	■	■
<b>DNA</b>	These products are tested and proven to be Human and Rodent DNA-free per the Lower Limit of Detection per 30 pg.	■	■	■
<b>Validated in the human identification workflow</b>	Exhibits a high degree of accuracy, precision and reproducibility for forensic applications such as DNA quantification, short tandem repeats (STR) amplification, and genotyping assays.			■

### 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. To receive notifications of product changes, register to receive changes through the following link [www.thermofisher.com/registercustomernotifications](http://www.thermofisher.com/registercustomernotifications).

All products are fully traceable by lot number. For a lot-specific certificate, please Contact Us/Technical Support ([Link](#)) and enter the product name or SKU.

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

**Ravi Gupta**  
Vice President/General Manager,  
Liquid Handling Solutions  
Laboratory Plastics Essentials

**Luis Perez**  
Director, Quality Assurance  
Laboratory Products

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