

Certificate of product line quality

Softfit-L product family

Thermo Fisher Scientific certifies that the Softfit-L 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	Sterile & PCR ready	Forensic ready
Non-regulated product	Based on the Intended Use and/or Indicates for Use, this product is not considered to be a medical device.	■	■
Materials	Products are produced with materials such as virgin polypropylene. No recycled materials are used in the manufacture of these products. Our polypropylene supplier does not use or intentionally incorporate the following agents into the materials used for production: Plasticizers (softeners/ phthalates), Melamine, Silicone, or Latex.	■	■
Production	Products are manufactured in a general environment.	■	■
Functional testing	Products undergo continuous quality controls regarding product function; this includes dimensional for visual inspection, dimensional checks, and functional inspection (weight of liquid).	■	■
Sterility	Sterile products are sterilized by e-beam 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-pyrogenic with a documented endotoxin level of less than 0.5 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.	■	■
Bisphenol A (BPA) free	BPA has not been used in the manufacturing process of the plastic in question.	■	■
Adenosine triphosphate (ATP) free	ATP has not been used in the manufacturing process of the plastic in question.	■	■

Certificate of product line quality

Soffit-L product family (continued)



Item	Description	Sterile & PCR ready	Forensic ready
Polymerase chain reaction (PCR) inhibitors	This product is certified to be free of PCR Inhibitors to < 30 pg 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 10^{-9} Kunitz unit/μl for RNase and 10^{-7} Kunitz unit/μl for DNase.	■	■
DNA	These products are tested and proven to be Human DNA and Mouse DNA free per the Lower Limit of Detection per 30 pg.	■	■
Validated in the human identification workflow	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



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.

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

ISO 9001
Certified

ISO 14001
Certified

ISO 13485
Certified

Learn more at thermofisher.com/fitforpurpose

thermo scientific