

Certificate of product line quality

Storage Plates product family

Thermo Fisher Scientific, Inc. certifies that the Storage Plate 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 virgin polypropylene tested and meeting the requirements of USP <661.1>. 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: Melamine, Silicone, or Latex.	■	■	■	■
USP Class VI, USP 88	The resin used to mold plates was tested and met the requirements of USP <88> Class VI plastics. Exclusion: Color-coding resin not tested.	■	■	■	■
Production	Products are manufactured in a controlled environment or ISO class 8 Clean room environment according to ISO 14644-1, depending on fit-for-purpose.	■	■	■	■
Functional testing	Products undergo continuous quality controls regarding product function; this includes dimensional checks, visual inspection, and packaging criteria.	■	■	■	■
Sterility	As part of this product family, there are both sterile and non-sterile products. For the Sterile products listed as part of this product family the following criteria applies: Sterilized by Gamma irradiation according to ISO 11137; 10 ⁻⁶ Sterility Assurance Level (SAL)		■		■
Sterilization dose audit	Audited quarterly according to ISO 11137.		■		■
Non-cytotoxic	This material was tested and shown to be non-cytotoxic per ISO 10993-5 or USP <87> requirements. Exclusion: Color-coding resin additives not tested.	■	■	■	■
Non-endotoxin	An extract from the lot was tested and certified non-pyrogenic with a documented endotoxin level of < 0.06 EU/ml in conformance with the Limulus Amebocyte Lysate (LAL) test method per USP <85>.		■		■

Certificate of product line quality

Storage Plates product family (continued)



Item	Description	Certified quality	Sterile	PCR ready	Sterile & PCR ready
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.	■	■	■	■
Polymerase chain reaction (PCR) inhibitors	This product is certified to be free of PCR Inhibitors to < 0.1 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 1.9×10^{-10} Kunitz unit/ μ L for RNase and 8×10^{-7} Kunitz unit/ μ L for DNase.		■	■	■
DNA	Products are tested and proven to be Human DNA free per the Lower Limit of Detection < 0.8 pg/ μ L.			■	■

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 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.

Julie Planchet
Vice President & General Manager,
Laboratory Plastics Essentials

Luis Perez
Director, Quality Assurance
Laboratory Products Division

Learn more at thermofisher.com/fitforpurpose

thermo scientific