

# Certificate of product line quality

## Matrix Storage Tube product family

Thermo Fisher Scientific, Inc. certifies that the Matrix Storage Tube 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	PCR ready	Sterile & PCR ready
<b>Non-regulated product</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>	All products are produced with materials such as virgin polypropylene copolymer. 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, or Latex.  This statement applies only to the Matrix Storage Tubes and not the racks.	■	■	■
<b>USP Class VI, USP 88</b>	The vials and closures were tested and met the requirements of USP <88> Class VI plastics.  <b>Exclusion:</b> Color-coding inserts not tested	■	■	■
<b>Production</b>	Products are manufactured in ISO 7 class clean room environment according to ISO 14644-1:2015.	■	■	■
<b>Functional testing</b>	Products undergo continuous quality controls at periodic intervals regarding product function; this includes dimensional checks, leak testing for seal integrity, barcode check (including readability, no duplicates, and matching as applicable) and packaging inspection.	■	■	■
<b>Sterility</b>	Sterile products are sterilized by gamma irradiation according to ISO 11137; 10 <sup>-3</sup> Sterility Assurance Level (SAL).			■
<b>Sterilization dose audit</b>	Audited quarterly according to ISO 11137.			■
<b>Non-cytotoxic</b>	The vials and closure material were tested and met the requirements of USP <87> MEM Elution test.  <b>Exclusion:</b> Green and purple caps	■	■	■
<b>Endotoxin (Pyrogen)</b>	This product has been sampled and tested and certified non-pyrogenic with a documented endotoxin level of less than 0.05 EU/ml in conformance with the Limulus Amebocyte Lysate (LAL) test method per USP <85>.	■	■	■

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## Matrix Storage Tube product family (continued)



Item	Description	Certified quality	PCR ready	Sterile & PCR ready
<b>Animal components</b>	Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathies (TSE) (EMEA 410/01 Compliant) regulatory statements. This statement applies only to the Matrix Storage Tubes and not the racks.	■	■	■
<b>Bisphenol A (BPA)</b>	BPA has not been used in the manufacturing process of the plastic in question. This statement applies only to the Matrix Storage Tubes and not the racks.	■	■	■
<b>Polymerase chain reaction (PCR) inhibitors</b>	This product is certified to be free of PCR Inhibitors to < 0.1 pg by amplification of a human DNA target sequence. qPCR is performed including the appropriate controls and all reactions are analyzed for a profile characteristic of qPCR inhibition by negative or delayed amplification relative to standards and controls as well as analysis of amplification plots. Test and control reactions must amplify the expected DNA targets with equivalent yield and purity to verify that the product is 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 $1.9 \times 10^{-10}$ Kunitz unit/ $\mu$ L for RNase and $8 \times 10^{-7}$ Kunitz unit/ $\mu$ L for DNase.		■	■
<b>DNA</b>	These products are tested and proven to be Human DNA free per the Lower Limit of Detection <1 pg.		■	■

### 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.

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