

# Certificate of product line quality

## Screw Cap Microcentrifuge Tubes product family

Thermo Fisher Scientific, Inc. certifies that the Thermo Scientific™ Screw Cap Microcentrifuge Tubes 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
<b>Non-regulated product (in the countries to which the product is currently sold)</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 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. Our material suppliers do not use or intentionally add the following during the manufacturing process: cadmium, lead, mercury, hexavalent chromium, PBB, PBDE, DEHP, BBP, DBP or DIBP.
<b>Plastic materials of constructions</b>	Per USP < 661.1 >, Identification, physicochemical and extractable metals (as listed in the chapter) tests.
<b>USP &lt;88&gt; Class VI Plastics</b>	The vials and closures material were tested and met the requirements of USP <88> Class VI plastics. <b>Exclusion:</b> O-ring.
<b>Production</b>	Products are manufactured in a controlled environment.
<b>Functional testing</b>	Products undergo continuous quality controls regarding product function; this includes dimensional checks and a visual inspection.
<b>Shelf life</b>	A five (5)-year shelf life from the date of manufacture is recommended; unless specified on the label.
<b>Non-cytotoxic</b>	The vials and closure material were tested and met the requirements of USP <87> MEM Elution test. <b>Exclusion:</b> O-ring.
<b>Non-pyrogenic</b>	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>.
<b>Animal components</b>	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.
<b>Bisphenol A (BPA) free</b>	BPA has not been used in the manufacturing process of the plastic in question.
<b>Leachables/extractables</b>	Manufactured without the use of slip agents, plasticizers, phthalates, and biocides. USP 665 Extractables and Leachables reports may be available upon request.

## 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 at [info.sandiego@thermofisher.com](mailto:info.sandiego@thermofisher.com).

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

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

Learn more at [thermofisher.com/fitforpurpose](http://thermofisher.com/fitforpurpose)

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