

Fit for Purpose designation

Sterile

Products with the Fit for Purpose designation Sterile are ideal when lab work requires assurance that products are free of living microorganisms and residual endotoxins (pyrogens) that can negatively affect your science. These products have been tested and meet the following criteria:

Description	Test method	Limit of detection
Sterile	E-beam or gamma irradiation or EtO gassing	Tested in accordance with ISO 11137; SAL varies by product
Free of endotoxins	Limulus Amebocyte Lysate (LAL) gel-clot or kinetic-turbidometric	Tested in accordance with USP 85; sensitivity varies by product

Products designated as Sterile have been sterilized using electron beam (E-beam), gamma irradiation or ethylene oxide gas processing to a minimum sterility assurance level (SAL) in accordance with ISO 11137. Additionally, our Sterile designated products are tested to be free of endotoxin contamination using the Limulus Amebocyte Lysate (LAL) gel-clot assay according to current FDA regulations and USP 85.

Thermo Scientific™ Sterile Fit for Purpose products are recommended for use with the following application areas and techniques:

Application areas

- Agriculture and aquaculture research
- Environmental monitoring
- Food and beverage quality control
- Medical research
- Microbiology
- Stem cell research
- Transgenic plant/animal studies
- Water quality control

Techniques

- Bacteria and yeast cultures
- Cell and tissue cultures



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.

Luis Perez
Director, Quality Assurance
Laboratory Products

ISO 9001
Certified

ISO 14001
Certified

ISO 13485
Certified

Learn more at thermofisher.com/fitforpurpose

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