

# Certificate of product line quality

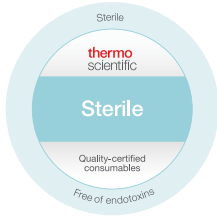
## Nalgene Sterile PETG and PET media bottles and closures product family

Thermo Fisher Scientific, Inc. certifies that the product family of Thermo Scientific™ Nalgene™ Sterile PETG and PET media bottles and closures have 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</b>	Based on the Intended Use and/or Indications for Use, this product family is not considered to be a medical device.
<b>Materials</b>	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. <b>Exclusion:</b> Septum material is silicone/PTFE.
<b>Plastic materials of construction</b>	Meets requirements of USP < 661 > physicochemical tests. <b>Exclusion:</b> Silicone/PTFE septa not tested.
<b>USP &lt;88&gt; Class VI</b>	The bottles and closures were tested and met the requirements of USP <88> Class VI plastics.
<b>Mutagenicity</b>	All components have been tested and were shown to be non-mutagenic according to the Ames Mutagenicity Test. <b>Exclusion:</b> PP closures and silicone/PTFE septa not tested.
<b>Production</b>	Products are manufactured in a controlled environment (PET) or ISO class clean room environment according to ISO 7 (PETG).
<b>Functional testing</b>	Products undergo continuous quality controls at periodic intervals regarding product function; this includes dimensional checks and leak testing for seal integrity.
<b>Particulate level</b>	Certified clean*: USP < 788 > Platinum clean*: 1/3 USP < 788 >
<b>Non-cytotoxic</b>	This material was tested and shown to be non-cytotoxic per ISO 10993-5 or USP <87> requirements.
<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 plastics in question.

\* Liquid particulate count levels are certified in accordance with the methods and controls established in USP < 788 >

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

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