

# Certificate of product line quality

## Nalgene Sterile HDPE Packaging Bottles and Closures product family

Thermo Fisher Scientific certifies that the product family of Thermo Scientific™ Nalgene Sterile HDPE Packaging Bottles and Closures have 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	Sterile
<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>Plastic materials of construction</b>	Meets requirements of USP < 661.1 > physicochemical tests.	■
<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>Production</b>	Products are manufactured in a controlled environment.	■
<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>Sterility</b>	Product was Gamma Irradiation Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. These sterile products have a shelf life of five years.	■
<b>Sterilization dose audit</b>	Audited quarterly according to ISO 11137.	■
<b>Non-cytotoxic</b>	This material was tested and shown to be non-cytotoxic per ISO 10993-5 or USP < 87 > requirements.	■
<b>Non-pyrogenic</b>	Tested for pyrogenicity and are determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 >.	■

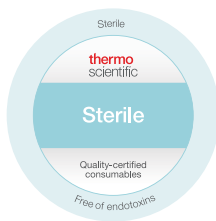
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## Nalgene Sterile HDPE Packaging Bottles and Closures product family (continued)



Item	Description	Sterile
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 plastics in question.	■
Leachables/Extractables	USP < 661.1 > test summaries available for the applicable resins.	■
Polymerase chain reaction (PCR) inhibitors	Product produced after Lot 1193361 is certified to be free of detectable RNase/DNase contamination. This test is performed using the nuclease assay method with a detection limit of $8 \times 10^{-7}$ Kunitz unit/ul for DNase and $1.9 \times 10^{-10}$ Kunitz unit/ul for RNase.	■
DNA	Product was determined to be free of human DNA using a detection limit of 30 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. 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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