

# Certificate of product line quality

## Nalgene Rapid-Flow Filters product family

Thermo Fisher Scientific, Inc. certifies that the Thermo Scientific™ Nalgene™ Rapid-Flow™ Filters 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: pore size 0.1 µm for products XXX-XX10, 0.2 µm for products XXX-XX20, 0.45 µm for products XXX-XX45, and 0.8 µm for products XXX-XX80.

Item	Description
<b>Non-regulated (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>Non-cytotoxic</b>	All component materials were tested and met the requirements of the USP <87> or ISO 10993-5 cytotoxicity test.
<b>USP &lt;88&gt; Class VI</b>	All component materials 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 regarding product function; this includes dimensional checks and functional testing.
<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>Bubble point</b>	Samples were tested according to an established procedure to determine the water bubble point of the product (isopropanol for PES products and 90mm 0.2µm SFCA products).
<b>Non-fiber releasing</b>	This product was manufactured using a microporous membrane which meets the criteria for “non-fiber” releasing filters as defined in 21 CFR 210.3 (b) (6) of the Food Additive Amendment of the U.S. Federal Food and Drug Act.
<b>Membrane gravimetric extractable</b>	The extractable level of the membrane is tested and reported as a weight percent of the membrane.
<b>Bacterial retention</b>	Filter membranes are quantitatively retentive of organisms using HIMA and/or ASTM methodologies.
<b>Flow rate</b>	Membrane samples are tested for water flow rate according to a standard procedure with values reported for each lot.

## 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.

**Dave D'Angelo**  
Vice President/General Manager,  
Labware, Clinical & Storage  
Laboratory Plastics Essentials

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

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

**thermo** scientific