

Part Number

Tel 585-586-8800 Fax 585-899-7605 75 Panorama Creek Drive, Rochester, NY 14625

Common Name

Product Certificate Thermo Scientific

Nalgene and Nunc Products

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694) in Monterrey Mexico.

The following information represents Product Certification for: Item#: 568-0020

Description

Description: FLTR, A-PES, 250ML, 50 MM, 0.2 Lot#: **1252453** Use Before: 03/28/2024

DMF#

Cytotoxicity

Viestale.	Ana Martinez
	Quality Manager

Certificate issued: 03/25/2019

Manufactured: 03/14/2019 USP Class VI FDA Compliance - 21 CFR

1-0014-82	COLLAR,FLT,45/50,MF75,HIPS,BLU	COMPONENT PART				
8-0077-18P	RESIN,PS,HIGH IMPACT,BLU,INJ	COLOR MIX	N/A	PASSED	PASSED	N/A
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-74	COLOR, BLUE, MULTI	COLORANT, BLUE, MULTI-RESIN	N/A	PA SSED	PASSED	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
1-0014-95	ADP,FLT,Q/D,LDPE,WHT,MF-75	COMPONENT PART				
8-0049-14P	RESIN,LDPE,WHT,INJ	COLOR MIX (LDPE, WHT, INJ)	N/A	N/A	N/A	N/A
8-0049-01	RESIN,LDPE,INJ	LOW-DENSITY POLYETHYLENE	9522	PASSED	PASSED	177.1520(a)(2)(i)
8-0099-26	COLOR,WHT,OLF	COLORANT, WHITE	N/A	N/A	N/A	178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking
1-1803-52	CLOS,45/430,HDPE,WHT,NALGE	COMPONENT PART				
8-0042-16P	RESIN, HDPE, WHT, INJ	COLOR MIX (RESIN, HDPE, WHT)	N/A	PASSED	PASSED	N/A
8-0042-01	RESIN, HDPE, INJ	HIGH-DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
8-0099-34	COLOR,WHT,MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620,178.3297, 181.28
1-0014-63	LOWER,FLT,250ML,45MM NK,ANON	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640
1-0014-42	COV,FLT,150/250mL,THERMO	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640
1-0014-91	UPPER,FLT,250 ML, MF-75, PS	COMPONENT PART				
8-0077-12	RESIN,PS,INJ,IBM	POLYSTYRENE	1623	PASSED	PASSED	177.1640



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The following information represents Product Certification for: Item#: 568-0020

Lot#: 1252453 Use Before: 03/28/2024 Ana Martinez Quality Manager

Certificate issued: 03/25/2019

Description: FLTR, A-PES, 250ML, 50 MM, 0.2 Manufactured: 03/14/2019

If N/A appears in any of the columns above it means the information is not available. Any item listed as "COMPONENT PART" will show blank in the DMF#, Cytotoxicity, USP Class VI, and FDA Compliance Information columns.

If the word "PASSED" appears in the USP Class VI column next to the resin listing, this material has passed USP Class VI requirements, latest Volume, as part of our initial test approval protocol.

If the word "PASSED" appears in the Cytotoxicity column next to the resin listing, this material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

Product was Gamma Irradiation Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product was determined to be non-pyrogenic at a level < 0.25 EU/ml per USP < 85 >.