ThermoFisher SCIENTIFIC

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Product Certificate

Thermo Scientific
Nalgene and Nunc Products

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485 (BSI Certificate Number: FM 653694) or ISO 9001 (BSI Certificate Number: FM 743358) in Rochester, NY, USA.

Alan E. Hatch
Sr. Quality Manager
11/24/2024

The following information represents Product Certification for: Item#: **342830-0113**

Description: **CLOS, MPV,ORANGE CODER,HDPE; 11MM, EBEAM** Lot#: **1416685** Use Before: **10/24/2029** Manufactured: **10/24/2024**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-3828-90	CLOS,HDPE,PACKAGING VIAL	COMPONENT PART				
8-0042-02	RESIN,HDPE,HF,INJ	HIGH DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a
1-3828-96	COLOR CODER,ORG,PKG VIAL	COMPONENT PART				
8-0077-14P	RESIN,PS,HIGH IMPACT,ORG,INJ	HIGH IMPACT PS, ORANGE	N/A	N/A	PASSED	N/A
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-36	COLOR,ORG,MULTI	COLORANT, ORANGE	N/A	N/A	N/A	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210

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 E-Beamed Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 > .

Product produced after Lot 582258 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 x 10^ -7 Kunitz unit/ul for DNase and 1.9 x 10^ -10 Kunitz unit/ul for RNase. This product was manufactured using virgin resin.