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 produced, inspected and found to be in compliance with product and quality specification requirements as documented in our ISO 13485:2003 Quality Management System (QMI-SAI Global File No. 1606319 and 1606321) in the USA.

Lisa Adams
Mgr. Quality Engineering

The following information represents Product Certification for: Item#: **342825-0115** Certificate issued: **03/13/2012**

Description: **CLOS,MPV,RED CODER, STER, AMB PPCO;11** Lot#: **1064755** Use Before: **02/28/2017** Manufactured: **02/28/2012**
MM

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-3828-84	CLOS,PPCO,PACKAGING VIAL,AMBER	COMPONENT PART				
8-0028-19P	RESIN,PPCO,RAD STAB,AMBER,INJ	COMPONENT PART				
8-0028-04	RESIN,PPCO,RAD STER,INJ	POLYPROPYLENE COPOLYMER	7478	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.1(a)except for cooking, (useconditions C-H)
8-0099-66	COLOR,AMBER,RAD. STAB.,	COLORANT, AMBER	N/A	N/A	N/A	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210
1-3828-99	COLOR CODER,RED,PKG VIAL	COMPONENT PART				
8-0077-30P	RESIN, PS, HI IMPACT, RED, INJ	COMPONENT PART				
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-98	COLOR,RED,LLDPE,NOT FDA	COLORANT, RED, NOT FDA	N/A	N/A	N/A	Not FDA

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 < 0.5 EU/ml as defined in "Guidelines on the Validation of the Limulus Amebocyte Lysate Test", as defined by the FDA (12/87) as an end product endotoxin test for human and animal parenteral drugs, biological products and medical devices. 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.