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 (FM 31464 by BSI) in the USA.

Robert Prescott
Mgr. QA/RA

The following information represents Product Certification for: Item#: **2019-0500**

Certificate issued: **04/16/2009**

Description: **SQ MEDIA BTL STRL PETG;500ML]]** Lot#: **1001728** Use Before: **04/28/2014** Manufactured: **04/01/2009**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0638-98P	BTL,500ML,SQ,N/M,PETG	COMPONENT PART				
8-0001-32	RESIN,PETG,IBM,EBM,INJ	COPOLYESTER, PETG NATURAL	9987	PASSED	PASSED	177.1315(b)(1) and 174.5
1-1803-21	CLOS,38/430,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, 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 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 by "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.