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 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 Monterrey, NL, MEX.

Ruben Deschamps
Sr. Quality Manager
03/29/2025

The following information represents Product Certification for: Item#: **342089-0004**

Description: **BOTTLE, N/M,HDPE,125ML,STR** Lot#: **1425952** Use Before: **03/28/2030** Manufactured: **03/28/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0423-82P	BTL,125ML,RND,N/M,HDPE	COMPONENT PART				
8-0042-31	RESIN,HDPE,IBM,EBM,EXT	HIGH-DENSITY POLYETHYLENE	3310	PASSED	PASSED	177.1520 (c) 3.2a
1-1811-43	CLOS,24/415,PP,WHT,NALGE	COMPONENT PART				
8-1001-49	PKG/MTL,CABLE TIE,5.64"X0.142"	COMPONENT PART				

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 per USP < 85 > .

Product produced after Lot 1195473 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. Product was determined to be free of human DNA using a detection limit of 30 pg.