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 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

June Gulisano
Sr. Quality Manager

The following information represents Product Certification for: Item#: **CE-N2019-1000**

Certificate issued: **01/07/2021**

Description: **CertPlatCln 1000mLPETG Btl,S,UltraLoPart** Lot#: **1305125** Use Before: **01/04/2023** Manufactured: **12/30/2020**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0638-99P	BTL,1L,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, 1620,178.3297, 181.28

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 to 10-6 SAL. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines.
Product was determined to be non-pyrogenic at a level of < 0.25 EU/ml per USP < 85 > . Particle count levels for each lot are certified to be at or below one-third of the allowable particulate limits according to the specification for Particulate Matter in Injectables, USP < 788 > , as documented in the Certificate of Processing.