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
06/09/2025

The following information represents Product Certification for: Item#: **CE-N3410-42**

Description: **CertPlatCln 10L PC Biotn S UltraLoPrtcl** Lot#: **7451091010** Use Before: **02/11/2030** Manufactured: **02/11/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0449-91	CLOS,48MM,Q/A,W/O SLRNG,PP,WHT	COMPONENT PART				
8-0028-16P	RESIN,PPCO,RAD STAB,WHITE,INJ	COLOR MIX (PPCO, RAD STAB,WHT)	N/A	PASSED	PASSED	N/A
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)
8-0099-34	COLOR,WHT,MULTI	COLORANT, WHITE	16513	PASSED	PASSED	177.1350, 1520, 1620,178.3297, 181.28
1-0449-04P	BIOTAINER,10L,PC	COMPONENT PART				
8-0056-35	RESIN,PC,BLUE,EBM/IBM,	POLYCARBONATE,BLUE,EBM/IBM	1562	PASSED	PASSED	177.1580

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.

This closure contains a silicone liner. The liner material meets requirements of CFR 21, Section 177.2600 of the Federal Food and Drug Act. The material has also been tested and shown to comply with USP Class VI requirements and has been shown to be non-cytotoxic.
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 < 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. Low - particulate processing, bacterial endotoxin and particle count testing for each lot are performed at: Thermo Fisher Scientific, 520 N. Main Street, Miami, OK 74354, as stated on the Certificate of Processing. Products have been subjected to 100% visual inspection of seal chamfer surfaces and were found to be free of defects, damage or other surface irregularities.

ANIMAL DERIVED MATERIALS (BSE/TSE) - All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 section 6.4. The purchased component(s) used in this product also comply with the latest revision of EMA/410/01 section 6.4.