ThermoFisher SCIENTIFIC

Tel 585-586-8800
75 Panorama Creek Drive, Rochester, NY 14625

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-E2099-0001**

Description: **Cert Plat Cln HDPE 30mL S Ultra LoPrtcl** Lot#: **7437910010** Use Before: **06/21/2029** Manufactured: **06/21/2024**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0423-70P	BTL,IP2,30ML,RND,N/M,HDPE; 1 OZ	COMPONENT PART				
8-0042-31	RESIN,HDPE,IBM,EBM,EXT	HIGH-DENSITY POLYETHYLENE	3310	PASSED	PASSED	177.1520 (c) 3.2a
1-1711-02	CLOS,20/415,PP,NAT,NALGE	COMPONENT PART				
8-0071-06	Resin,PP,Inj	POLYPROPYLENE, INJECTION	9988	PASSED	PASSED	177.1520(a)(1)(i), (c)1.1a,177.1520(b), (use conditionsA-H)

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 < 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.

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.