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
06/10/2025

The following information represents Product Certification for: Item#: **4112-2000**

Description: **STERILE DISPO FLASK 2L, PETG** Lot#: **1429494** Use Before: **05/20/2030** Manufactured: **05/20/2025**

| Part Number | Description | Common Name | DMF# | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|---|---|---|---|---|---|---|
| 1-1803-52 | CLOS,45/430,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 |
| 1-2831-95P | FLASK,DISP,2L,PETG | COMPONENT PART | | | | |
| 8-0001-32 | RESIN,PETG,IBM,EBM,INJ | COPOLYESTER, PETG NATURAL | 9987 | PASSED | PASSED | 177.1315(b)(1) and 174.5 |

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 > .

The closure is produced using HDPE resin and white colorant. Both materials have been tested and shown to comply with USP Class VI requirements and to be non-cytotoxic. The HDPE resin meets requirements of FDA regulation 21 CFR section 177.1520(c)3.1a and the white colorant meets sections 177.1520, 177.1350, 177.1620, 178.3297, 181.28.

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.