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
05/07/2026

The following information represents Product Certification for: Item#: **342035-0010**

Description: **PETG BTL W/LINED CLSR,10ML,STR** Lot#: **1449073** Use Before: **03/12/2031** Manufactured: **03/12/2026**

| Part Number | Description | Common Name | DMF# | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|---|---|---|---|---|---|---|
| 1-0456-82P | VIAL,SERUM,10ML,PETG | COMPONENT PART | | | | |
| 8-0001-32 | RESIN,PETG,IBM,EBM,INJ | COPOLYESTER, PETG NATURAL | 9987 | PASSED | PASSED | 177.1315(b)(1) and 174.5 |
| 1-1860-02 | CLOS ASSY,20MM WHT,W/BLU LINER | 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 >.

The closure contains a liner. The liner material is a foamed LDPE core between two facings of solid HDPE. The liner material has passed USP Class VI and cytotoxicity testing.

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.

DOMINIQUE DUTSCHER SAS