

Tel 585-586-8800 75 Panorama Creek Drive, Rochester, NY 14625 Product Certificate
Thermo Scientific
Nalgene and Nunc Products

Manufactured:

Alm E Hatel

Alan E. Hatch Sr. Quality Manager 03/05/2025

02/17/2025

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.

The following information represents Product Certification for: Item#: DS3132-0063

Description: CENT. SEALING CAP PP;63MM Lot#: 7451713010

| Part Number | Description                  | Common Name                | DMF#  | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR                                     |
|-------------|------------------------------|----------------------------|-------|--------------|--------------|---|
| 1-2412-81   | CLOS,SEALING CAP,63MM,PP,WHT | COMPONENT PART             |       |              |              |   |
| 8-0071-11P  | RESIN,PP,WHI,INJ             | POLYPROPYLENE, WHITE, INJ. | N/A   | PASSED       | PASSED       | N/A   |
| 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) |
| 8-0099-34   | COLOR,WHT,MULTI              | COLORANT, WHITE            | 16513 | PASSED       | PASSED       | 177.1350, 1520, 1620,178.3297,<br>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.

This sealing closure contains a silicone gasket. The gasket 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.