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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 13485:2003 (BSI Certificate Number: FM 653694) in the USA.

**Barry Srolis** 

Sr. Quality Manager

The following information represents Product Certification for: Item#: 2015-2000

Certificate issued: 06/08/2018

Description: BOTTLE SQUARE PC;2000ML Lot#: 1231830 Manufactured: 05/30/2018

| Part Number | Description              | Common Name                | DMF#  | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR   |
|-------------|--------------------------|----------------------------|-------|--------------|--------------|---|
| 1-0639-83P  | BTL,2L,SQ,N/M,PC,2 cav   | COMPONENT PART             |       |              |              |   |
| 8-0056-01   | RESIN,PC,INJ,IBM         | POLYCARBONATE              | 1562  | PASSED       | PASSED       | 177.1580  |
| 1-1821-21   | CLOS,53BSTD,PP,WHT,NALGE | 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),<br>(c)1.1a,177.1520(b), (use<br>conditionsA-H) |
| 8-0099-34   | COLOR,WHT,MULTI          | COLORANT, WHITE            | 16513 | PASSED       | PASSED       | 177.1350, 1520, 1620,178.3297, 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.