

Fax 585-899-7605 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 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 Monterrey Mexico.

The following information represents Product Certification for: Item#: 595-4520

Description: BTLTOP,A-PES,45MM,500ML,75MM Lot#: **1250736** Use Before: 02/28/2024 Manufactured: 02/18/2019

| Nosale: | Ana Martinez Quality Manager | | | |
|-----------------|-------------------------------|--|--|--|
| Certificate is: | sued: 02/24/2019 | | | |

| Part Number | Description | Common Name | DMF# | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|-------------|--------------------------------|-----------------------------|------|--------------|--------------|--|
| 1-0014-86 | COLLAR,FLT,45/75,MF75,HIPS,BLU | COMPONENT PART | | | | |
| 8-0077-18P | RESIN,PS,HIGH IMPACT,BLU,INJ | COLOR MIX | N/A | PASSED | PASSED | N/A |
| 8-0077-13 | RESIN,PS,HIGH IMPACT,INJ | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 8-0099-74 | COLOR, BLUE, MULTI | COLORANT, BLUE, MULTI-RESIN | N/A | PASSED | PASSED | 177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210 |
| 1-0014-95 | ADP,FLT,Q/D,LDPE,WHT,MF-75 | COMPONENT PART | | | | |
| 8-0049-14P | RESIN,LDPE,WHT,INJ | COLOR MIX (LDPE, WHT, INJ) | N/A | N/A | N/A | N/A |
| 8-0049-01 | RESIN,LDPE,INJ | LOW-DENSITY POLYETHYLENE | 9522 | PASSED | PASSED | 177.1520(a)(2)(i) |
| 8-0099-26 | COLOR,WHT,OLF | COLORANT, WHITE | N/A | N/A | N/A | 178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking |
| 1-0014-44 | COV,FLT,500mL,THERMO | COMPONENT PART | | | | |
| 8-0077-12 | RESIN,PS,INJ,IBM | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 1-0014-90 | UPPER,FLT,500 ML, MF-75, PS | COMPONENT PART | | | | |
| 8-0077-12 | RESIN,PS,INJ,IBM | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 1-0014-95 | ADP,FLT,Q/D,LDPE,WHT,MF-75 | COMPONENT PART | | | | |
| 8-0049-14P | RESIN,LDPE,WHT,INJ | COLOR MIX (LDPE, WHT, INJ) | N/A | N/A | N/A | N/A |
| 8-0049-01 | RESIN,LDPE,INJ | LOW-DENSITY POLYETHYLENE | 9522 | PASSED | PASSED | 177.1520(a)(2)(i) |
| 8-0099-26 | COLOR,WHT,OLF | COLORANT, WHITE | N/A | N/A | N/A | 178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking |



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Description: BTLTOP, A-PES, 45MM, 500ML, 75MM

Lot#: **1250736** Use Before: **02/28/2024** Manufactured:

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 < 0.25 EU/ml per USP < 85 > .

02/18/2019