

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

Manufactured:

Alm E Hatch

Alan E. Hatch Sr. Quality Manager 06/11/2025

06/04/2025

The following information represents Product Certification for: Item#: 165306

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or

management system which is compliant to ISO 13485 (BSI Certificate Number: FM 653694)

distributed according to the requirements of product and quality specifications as maintained in our quality

Description: 96OBP POLYMER WHITE CC W/LID Lot#: 1430306

or ISO 9001 (BSI Certificate Number: FM 743358) in Rochester, NY, USA.

DMF# Description Common Name Cytotoxicity USP Class VI FDA Compliance - 21 CFR Part Number COMPONENT PART 009302F01P 960BP POLYMER BOTTM NUNC WHITE 14203MRP RESIN, PHANTOM, MIX, WHITE, PS COMPONENT PART 8-0077-05 RESIN, POLYSTYRENE PS, NATURAL, BASE RESIN 18492 N/A PASSED 177.1640 14166MR MASTERBATCH, WHITE (A/S 56022 COLORANT, WHITE, INJ. N/A N/A N/A N/A 009326B00 LID, S/S PLATE, NUNC, PS, CLR COMPONENT PART RESIN.POLYSTYRENE NATURAL, POLYSTYRENE, INJ. 177.1640 14149MR 18492 PASSED PASSED

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 > .