

Tel 585-586-8800 Fax 585-899-7605 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 and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694) in the USA.

Dem Delisono June Gulisano Sr. Quality Manager

Certificate issued: 05/03/2019

Description: BOTTLE SQUARE PPCO; 250 ML

The following information represents Product Certification for: Item#: 2016-0250

Lot#: **1253162** 

Manufactured: 04/22/2019

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0636-93P	BTL,250ML,SQ,N/M,PP	COMPONENT PART				
8-0028-03	RESIN, PPCO, IBM, EBM	POLYPROPYLENE COPOLYMER	6345	PASSED	PASSED	177.1520 (a)(3)(i) & (c)3.2(a)(use conditions A-H)
1-1811-07	CLOS,38/430,PP,NAT,NALGE	COMPONENT PART				
8-0071-06	Resin, PP, Inj	POLYPROPYLENE, INJECTION	9988	PA SSED	PASSED	177.1520(a)(1)(i), (c)1.1a,177.1520(b), (use conditionsA-H)

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.