

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 (BSI Certificate Number: FM 653694)

Alan E. Hatch Sr. Quality Manager

The following information represents Product Certification for: Item#: 2100-0004

or ISO 9001 (BSI Certificate Number: FM 743358) in the USA.

Description: BTL W/M FEP;4OZ,125ML Lot#: 1396346 Manufactured: 11/02/2023

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1843-83	CLOS,33/415,ETFE,NAT,NALGE	COMPONENT PART				
8-0008-01	RESIN,ETFE,INJ	ETHYLENE- TETRAFLUOROETHYLENE	N/A	PASSED	PASSED	177.1550 at temperaures up to 121C
1-0605-96PP	BTL,125ML,RND,W/M,FEP	COMPONENT PART				
8-0015-36	RESIN, FEP, EBM	RESIN, FEP, EBM	N/A	PASSED	PASSED	177.1550

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.