

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

Alm E Hatch

Alan E. Hatch Sr. Quality Manager 06/14/2025

06/11/2025

Manufactured:

The following information represents Product Certification for: Item#: 3119-0030

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: CENTTUBE OAKRIDGE PPCO;30ML Lot#: 1430773

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

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-1711-02	CLOS,20/415,PP,NAT,NALGE	COMPONENT PART				
8-0071-06	Resin, PP, Inj	POLYPROPYLENE, INJECTION	9988	PASSED	PASSED	177.1520(a)(1)(i), (c)1.1a,177.1520(b), (use conditionsA-H)
1-2061-96P	TUBE, CNTFG, 30ML, PPCO, OAK/RDG	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)

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.

ANIMAL DERIVED MATERIALS (BSE/TSE) - All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 section 6.4.