

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 06/19/2025

06/12/2025

Manufactured:

The following information represents Product Certification for: Item#: 3114-0050

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: CENT TUBE OAK RIDGE FEP;50ML Lot#: 1430669

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

Description Common Name DMF# Cytotoxicity USP Class VI FDA Compliance - 21 CFR Part Number CLOS,24/415,ETFE,NAT,NALGE COMPONENT PART 1-1843-81 RESIN, ETFE, INJ PASSED PASSED 8-0008-01 ETHYLENE-N/A 177.1550 at temperaures up to TETRAFLUOROETHYLENE 121C 1-2062-97P TUBE, CNTFG, 50ML, FEP, OAK/RDG 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.