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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 13485:2003 (BSI Certificate Number: FM 653694) in the USA.

Barry Srolis
Sr. Quality Manager

Manufactured:

181.28

The following information represents Product Certification for: Item#: 312084-9025

Certificate issued: 02/05/2018

01/30/2018

Description: BTL PKG TRANS AMBER HDPE;1/4OZ Lot#: 1221805

DMF# Description **Common Name** Cytotoxicity **USP Class VI** FDA Compliance - 21 CFR Part Number COMPONENT PART 1-0435-61P BTL,8ML,RND,N/M,HDPE,TRANS **AMBER** 8-0042-34P RESIN, HDPE, TRSL AMB, IBM, EBM COLOR MIX (HDPE, TRSL AMB) N/A **PASSED** N/A N/A 8-0042-31 RESIN, HDPE, IBM, EBM, EXT HIGH-DENSITY POLYETHYLENE 3310 **PASSED PASSED** 177.1520 (c) 3.2a 8-0099-16 COLOR, TRSL AMB, OLF COLORANT, TRSL. AMBER 20858 N/A N/A 177.1520, 178.2010, 3297 CLOS,20/415,PP,AMB,NALGE 1-1811-62 COMPONENT PART 8-0071-14P RESIN.PP.AMB.INJ 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) 8-0097-17 COLOR, AMBER, MULTI COLORANT, OPAGUE, AMBER 24299 **PASSED PASSED** 177.1520, 177.1350,178.3297,

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.