ThermoFisher SCIENTIFIC

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Product Certificate

Thermo Scientific
Nalgene and Nunc Products

Thermo Fisher Scientific hereby certifies that the product identified below is produced, inspected and found to be in compliance with product and quality specification requirements as documented in our ISO 13485:2003 Quality Management System (QMI-SAI Global File No. 1606319 and 1606321) in the USA.

Tresia O'Shea
Manager, Regulatory Compliance

The following information represents Product Certification for: Item#: **2105-0004**

Certificate issued: **07/01/2014**

Description: **BTL W/M PP;4OZ,125ML]]**

Lot#: **1123519**

Manufactured: **06/12/2014**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0631-96P	BTL,125ML,RND,W/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)
1-1811-06	CLOS,38/415,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)

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.

Resin was tested and is in compliance with European Pharmacopoeia monograph 3.1.6 as stated by the resin manufacturer.