ThermoFisher SCIENTIFIC

Tel 585-586-8800
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 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) or ISO 9001 (BSI Certificate Number: FM 743358) in Monterrey, NL, MEX.

Ruben Deschamps
Sr. Quality Manager
06/10/2025

The following information represents Product Certification for: Item#: **177402**

Description: **CHAMBER SLIDE, 8 WELL GLASS** Lot#: **1429818** Manufactured: **05/23/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
0-580-98	CHAMBER TC 8-CELL	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640
0-583-98	CHAMBER TC COVER	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640
8-1030-99 0812	LABEL,STOCK,F/G,ORDER,NUNC %	COMPONENT PART				
8-1030-99 0812	LABEL,STOCK,F/G,ORDER,NUNC %	COMPONENT PART				
120225LE	Silicone,Dow,MDX4-4210,Permnox	SILICONE ADHESIVE	2811	PASSED	PASSED	177.2600

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.

Product has been ETO Sterilized. Product was released per ANSI/AAMI/ISO 11135 guidelines. Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP < 85 > .

This product is in compliance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. CE

Product Certificate Inquires should be directed to: CertificateMty@Thermofisher.com