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.

Robert Prescott
Mgr. QA/RA

The following information represents Product Certification for: Item#: **177410**

Certificate issued: **03/02/2011**

Description: **CHAMBER SLIDE, 1 WELL PERMNX]]** Lot#: **1041479** Use Before: **02/28/2016** Manufactured: **02/20/2011**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
0-583-98	CHAMBER TC COVER	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640
0-596-98	CHAMBER TC 1-CELL	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640
0003898	SLIDE PERMANOX	COMPONENT PART				
7002MR	RESIN,TPX,RT18XB	TPX,RT18XB	N/A	N/A	N/A	N/A
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 as defined by "Guideline on the Validation of the Limulus Amebocyte Lysate Test," as defined by the FDA (12/87), as an end product endotoxin test for human and animal parenteral drugs, biological products and medical devices. This product is in compliance to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.