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 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 (BSI Certificate Number: FM 653694) or ISO 9001 (BSI Certificate Number: FM 743358) in the USA.

Alan E. Hatch
Sr. Quality Manager

The following information represents Product Certification for: Item#: **150260**

Description: **IVF Center Well Dish** Lot#: **1394531** Use Before: **10/24/2028** Manufactured: **10/24/2023**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0025-87P	IVF CENTER WELL DISH	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640
1-0025-88P	IVF CENTER WELL LID	COMPONENT PART				
14149MR	RESIN,POLYSTYRENE	NATURAL, POLYSTYRENE, INJ.	18492	PASSED	PASSED	177.1640

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.

The product is tested using the LAL-test and certified non-pyrogenic with a documented endotoxin level of less than 20 Endotoxin Units/device (0.5 Endotoxin Units/ml) as stated in the USP < 85 > .

The product passed the Mouse Embryo Assay (MEA-test) - Blastocyst formation rate of greater than or equal to 80% for fully expanded blastocysts both in test and control after 96 hours. The embryo toxicity test is a release test and the product will only be sold if it has passed satisfactorily.

Sterility is obtained through irradiation according to ISO 11137 (sterilization of health care products - requirements for validation and routine control - radiation sterilization) with SAL 10^-6. Caution: Only contents of unopened or undamaged packages are guaranteed sterile.

The product is CE Marked according to EU Medical Device Directive, 93/42/EC, as amended and is registered as a class II device as "Assisted Reproduction Labware", product code MQK.

The material has successfully passed the mutation test (Ames Salmonella, microsome assay) according to the OECD Guideline for testing of chemicals No. 471.