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
08/03/2025

The following information represents Product Certification for: Item#: **377267**

Description: **1.8MLCRYOTBE RND IN TD STRFT** Lot#: **1430897** Manufactured: **06/27/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0633-10	Cryotube 1,8 ml, starfoot	COMPONENT PART				
69436	RESIN, PP, HD810MO	COMPONENT PART				

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.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 761244 R000

Manufacturer: Nalge Nunc International Corporation, a part of Thermo Fisher Scientific Inc.

Address:
75 Panorama Creek Drive
Rochester
New York
14625
USA

Single Registration Number: US-MF-000026915

EU Authorised Representative: Nunc A/S, Thermo Fisher Scientific

Address:
Kamstruvej 90
Roskilde
DK-4000
Denmark

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-01-17**

Current Issue Date: **2024-01-17**

Starting Validity Date: **2024-01-17**

Expiry Date: **2029-01-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 761244 R000

Device Schedule: Class A sterile devices

Device(s)	Risk Classification
IVR 0803 – Sterile specimen receptacles	Class As
For Class A sterile devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issue Date: **2024-01-17**

Current Issue Date: **2024-01-17**

Starting Validity Date: **2024-01-17**

Expiry Date: **2029-01-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 761244 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3576522	Issued

First Issue Date: **2024-01-17**

Current Issue Date: **2024-01-17**

Starting Validity Date: **2024-01-17**

Expiry Date: **2029-01-16**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 775707 R000

Manufacturer: Nalge Nunc International Corporation

Address:
75 Panorama Creek Drive
Rochester
New York
14625
USA

Single Registration Number: US-MF-000026915

EU Authorised Representative: Nunc A/S

Address:
Kamstrupvej 90
DK-4000 Roskilde
Denmark

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-11-20**

Current Issue Date: **2024-11-20**

Starting Validity Date: **2024-11-20**

Expiry Date: **2029-11-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 775707 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Nunc™ IVF Center Well Dish	Class IIa
Nunc™ IVF ICSI Dish	Class IIa

First Issue Date: **2024-11-20**

Current Issue Date: **2024-11-20**

Starting Validity Date: **2024-11-20**

Expiry Date: **2029-11-19**

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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 775707 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3730398	Issued

First Issue Date: **2024-11-20**

Current Issue Date: **2024-11-20**

Starting Validity Date: **2024-11-20**

Expiry Date: **2029-11-19**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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