

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

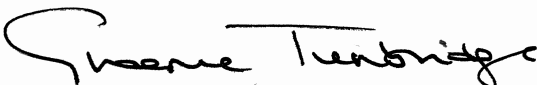
Address:

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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.