

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 656039**

Issued To:

**Nalge Nunc International Corporation
A Part of Thermo Fisher Scientific
75 Panorama Creek Drive
Rochester
New York
14625
USA**

In respect of:

Design and manufacture of sterile, single-use dishes for in vitro fertilization

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Albert Roossien, Regulatory Lead

First Issued: **2017-01-19**Date: **2019-03-06**Expiry Date: **2023-02-13**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Nunc A/S Thermo Fisher Scientific Kamstruvej 90 Roskilde DK-4000 Denmark	EU Representative
Sterigenics 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
19 January 2017	8555632	First issue. Transfer from another Notified Body.
08 February 2018	8863816	Certificate renewal. Removal of significant subcontractors Nalge Nunc International, Fairport; Nalge Nunc International, Rochester; Thermo Fisher Scientific Mexico.
Current	8678773	Traceable to NB 0086.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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