

# EC Certificate - Full Quality Assurance System

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

**No.** CE 550567  
**Issued To:** **STERIS MEXICO, S. de R.L. de C.V.**  
**Avenida Avante 790**  
**Parque Industrial Guadalupe**  
**Guadalupe**  
**Nuevo León**  
**67190**  
**Mexico**

In respect of:

**The design and manufacture of steam sterilization systems.**

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-05-29**

Date: **2019-05-27**

Expiry Date: **2024-05-26**

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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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## Supplementary Information to CE 550567

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NBOG code(s)	Device Description	Intended purpose
<b>Class IIb</b>		
MD 1107	Steam Sterilizer	Sterilization of medical devices.

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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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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**

STERIS Corporation  
5960 Heisley Road  
Mentor  
Ohio  
44060  
USA

**Design**  
**Regulatory Compliance**

STERIS Ireland Limited  
IDA Business & Technology Park  
Tullamore  
Co. Offaly  
R35 X865  
Ireland

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 550567**  
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Date	Reference Number	Action
29 May 2009	7373112	First Issue. Transfer from another Notified Body.
25 August 2010	7572159	Certificate reissue due to removal of STERIS Erie site and the addition of STERIS Mentor site as the significant subcontractor for design and regulatory compliance.
28 September 2012	7905822	Replacement of EU Representative with STERIS Ltd., Leicester, UK.
08 April 2014	8083388	Certificate Renewal Change of scope from "The design and manufacture of sterilization systems" to "The design and manufacture of steam, EO and VHP sterilization systems".
03 January 2019	8935067	Traceable to NB 0086.
Current	9720854	Certificate Renewal. Removal of EO and VHP sterilizers from scope. Change of EU Representative. Addition of device table.