By Royal Charter

# 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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**Supplementary Information to CE 550567**

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| NBOG code(s) | Device Description | Intended purpose |
|---|---|---|
| **Class IIb** | | |
| MD 1107 | Steam Sterilizer | Sterilization of medical devices. |

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

# List of Significant Subcontractors

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

| | |
|---|---|
| Certificate No: | **CE 550567** |
| Date: | **2019-05-27** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| STERIS Corporation<br>5960 Heisley Road<br>Mentor<br>Ohio<br>44060<br>USA | **Design**<br>**Regulatory Compliance** |
| STERIS Ireland Limited<br>IDA Business & Technology Park<br>Tullamore<br>Co. Offaly<br>R35 X865<br>Ireland | **EU Representative** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 550567**

Date: **2019-05-27**

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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<br>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.<br>Addition of device table. |