

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 701147
Issued To: **Sterile Supplies Limited**
SDU, Level 2
Salisbury District Hospital
Odstock Road
Salisbury
SP2 8BJ
United Kingdom

In respect of:

Those aspects of manufacture related to securing and maintaining sterility by moist heat in the assembly of theatre trays and procedure packs in accordance with Article 12 of the Medical Device Directive

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive.

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: **2019-02-26**

Date: **2021-02-01**

Expiry Date: **2024-02-25**

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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

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

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 701147**
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Date	Reference Number	Action
26 February 2019	9659483	First Issue.
11 March 2019	9653302	Traceable to NB 0086.
Current	3346826	Addition of Steris Ireland Limited as an EU representative.

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