

# 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):



Albert Roossien, Regulatory Lead

First Issued: **2019-02-26**

Date: **2019-03-11**

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

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Page 1 of 1

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.

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.

# EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
26 February 2019	9659483	First Issue.
Current	9653302	Traceable to NB 0086.

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Page 1 of 1

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