

# EC Certificate - Production Quality Assurance

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

**No.** CE 701944  
**Issued To:** Synergy Health (UK) Ltd  
Princess Royal University Hospital  
Sterile Services  
Farnborough Common  
Orpington  
Kent  
BR6 8ND  
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: **2019-06-07**

Date: **2019-06-07**

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

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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.

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## Certificate History

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Date	Reference Number	Action
Current	9666806	First Issue.

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Page 1 of 1

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