

EC Certificate - Production Quality Assurance

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

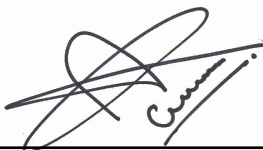
No. CE 671619
Issued To: Synergy Health (UK) Ltd
Unit C, Tiber Way
Meridian Business Park
Leicester
LE19 1QP
United Kingdom

In respect of:

Those aspects of manufacture related to securing and maintaining sterility by moist heat in the assembly of procedure packs and surgical instrument sets following Article 12 of the 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: **2018-06-29**

Date: **2019-03-11**

Expiry Date: **2021-03-27**

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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.

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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Certificate History

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| Date | Reference Number | Action |
|--------------|------------------|---|
| 29 June 2018 | 8714908 | First issue. Transfer from another Notified Body. |
| Current | 8857453 | Traceable to NB 0086. |

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