

EC Certificate - Production Quality Assurance

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

No. CE 671613
Issued To: Synergy Health (UK) Ltd
Overbrook Lane
Knowsley Business Park
Knowsley
Merseyside
L34 9FB
United Kingdom

In respect of:

Those aspects of manufacture related to obtaining sterility by moist heat in the assembly of theatre trays, and procedure trays 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-06-29**

Date: **2019-09-23**

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

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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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Certificate History

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Date	Reference Number	Action
29 June 2018	8714888	First Issue. Transfer from another notified body.
11 March 2019	8857452	Traceable to NB 0086.
Current	3072155	Certificate Renewal

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