

EC Certificate - Production Quality Assurance

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

No. CE 671631
Issued To: Synergy Health (UK) Ltd
Portman Road
Reading
Berkshire
RG30 1AH
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: **2021-11-04**

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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.

EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
29 June 2018	8714918	First Issue. Transfer from another notified body.
Current	8856921	Traceable to NB 0086.

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