

EC Certificate - Production Quality Assurance

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

No. CE 671647
Issued To: Synergy Health (UK) Ltd
Tameside General Hospital
Fountain Street
Ashton-under-Lyne
Lancashire
OL6 9RW
United Kingdom

In respect of:

Those aspects of manufacture related to obtaining sterility by moist heat in the assembly of theatre instrument sets and procedure packs 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: **2022-05-16**

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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.

EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
29 June 2018	8714961	First Issue. Transfer from another notified body.
Current	8857456	Traceable to NB 0086.

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