

EC Certificate - Production Quality Assurance

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

No.**CE 709834**

Issued To:

**Synergy Health (UK) Ltd
Central Sterile Services Department
Kings College Hospital NHS Trust
Kings Dental Institute
Bessemer Road, London
SE5 9RS
United Kingdom**

In respect of:

Those aspects of manufacture related to securing and maintaining sterility by moist heat in the assembly of instrument sets 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: **2019-04-12**Date: **2019-04-12**Expiry Date: **2024-04-11**

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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
Current	9754986 9754989	First issue.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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