By Royal Charter

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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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 671619**

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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.