

# EC Certificate - Production Quality Assurance

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

**No.****CE 671655****Issued To:**

**Synergy Health (UK) Ltd  
Pegasus House, Tilson Road  
Roundthorn Industrial Estate  
Wythenshawe  
M23 9GF  
United Kingdom**

In respect of:

**Those aspects of manufacture related to securing and maintaining sterility by moist heat and vaporized hydrogen peroxide in the assembly of procedure packs and instrument sets 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: **2018-06-29**

Date: **2020-04-19**

Expiry Date: **2022-12-13**

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 671655**  
 Date: **2020-04-19**  
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**Pegasus House, Tilson Road**  
**Roundthorn Industrial Estate**  
**Wythenshawe**  
**M23 9GF**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Tameside General Hospital Fountain Street Ashton-under-Lyne Lancashire OL6 9RW United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Units 4-5 Mallard Way Strathclyde Business Park Bellshill Lanarkshire ML4 3BF United Kingdom	<b>Gas Plasma Sterilization Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Royal Derby Hospital SSD Uttoxeter Road Derby DE22 3NE United Kingdom	<b>Moist Heat Sterilization Packaging</b>

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**M23 9GF**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Central Sterile Services Department Kings College Hospital NHS Trust Kings Dental Institute Bessemer Road, London SE5 9RS United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Epsom SSD, Epsom General Hospital Dorking Road Epsom Surrey KT18 7EG United Kingdom	<b>Moist Heat Sterilization Packaging</b>

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**United Kingdom**

### Subcontractor:

### Service(s) supplied

Synergy Health (UK) Ltd  
 Diana Princess of Wales Hospital  
 Scartho Road  
 Grimsby  
 Lincolnshire  
 DN33 2BA  
 United Kingdom

**Moist Heat Sterilization**  
**Packaging**

Synergy Health (UK) Ltd  
 HSDU Royal Surrey County Hospital  
 Egerton Road  
 Guildford  
 Surrey  
 GU2 7XX  
 United Kingdom

**Gas Plasma Sterilization**  
**Moist Heat Sterilization**  
**Packaging**

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**M23 9GF**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Northwick Park & St Marks Hospital HSDU Harrow Middlesex HA1 3UJ United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Sterile Services Department, Gate 7 Homerton University Hospital NHS Homerton Row Greater London E9 6SR United Kingdom	<b>Moist Heat Sterilization Packaging</b>

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**M23 9GF**  
**United Kingdom**

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Overbrook Lane Knowsley Business Park Knowsley Merseyside L34 9FB United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Unit C, Tiber Way Meridian Business Park Leicester LE19 1QP United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Lincoln County Hospital Greetwell Road Lincoln LN2 5QY United Kingdom	<b>Moist Heat Sterilization Packaging</b>

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**M23 9GF**  
**United Kingdom**

**Subcontractor:****Service(s) supplied**

Synergy Health (UK) Ltd  
Princess Royal University Hospital Sterile Services  
Farnborough Common  
Orpington  
Kent  
BR6 8ND  
United Kingdom

**Moist Heat Sterilization  
Packaging**

Synergy Health (UK) Ltd  
Portman Way  
Reading  
Berkshire  
RG30 1AH  
United Kingdom

**Moist Heat Sterilization  
Packaging**

Synergy Health (UK) Ltd  
Unit 6, Parkway One  
Parkway Drive  
Sheffield  
S9 4WU  
United Kingdom

**Gas Plasma Sterilization  
Moist Heat Sterilization  
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**United Kingdom**

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Sterile Services Department, Royal London Hospital Stepney Way Whitechapel Greater London E1 1BB United Kingdom	<b>Moist Heat Sterilization Packaging</b>
Synergy Health (UK) Ltd Sterile Services Unit, New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom	<b>Gas Plasma Sterilization Moist Heat Sterilization Packaging</b>

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# EC Certificate - Production Quality Assurance

## Certificate History

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Date	Reference Number	Action
29 June 2018	8715012	First Issue. Transfer from another notified body.
11 March 2019	8857460	Traceable to NB 0086.
Current	3126253	Extension to scope to include sterilization by vaporized hydrogen peroxide. Administrative scope updates to align with standard BSI scope wording. Addition of Synergy Health (UK) Ltd subcontractor locations in Ashton-under-Lyne, Bellshill, Bessemer Road (London), Derby, Epsom, Grimsby, Guildford, Harrow, Homerton Row, Knowsley, Leicester, Lincoln, Orpington, Reading, Sheffield, Whitechapel and Wolverhampton.

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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.