

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: **2021-01-20**

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.

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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:

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 Date: **2021-01-20**
 Issued To: **Synergy Health (UK) Ltd**
Pegasus House, Tilson Road
Roundthorn Industrial Estate
Wythenshawe
M23 9GF
United Kingdom

Subcontractor:	Service(s) supplied
STERIS Ireland Limited IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland	EU Representative
Synergy Health (UK) Ltd Royal Derby Hospital SSD Uttoxeter Road Derby DE22 3NE United Kingdom	Moist Heat Sterilization Packaging
Synergy Health (UK) Ltd Sterile Services Unit, New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom	Hydrogen peroxide sterilization Moist Heat Sterilization Packaging

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M23 9GF
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

Hydrogen peroxide sterilization
Moist Heat Sterilization
Packaging

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

Hydrogen peroxide sterilization
Moist Heat Sterilization
Packaging

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

Moist Heat Sterilization
Packaging

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Wythenshawe
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 Lincoln County Hospital Greetwell Road Lincoln LN2 5QY United Kingdom	Moist Heat Sterilization Packaging
Synergy Health (UK) Ltd Unit C, Tiber Way Meridian Business Park Leicester LE19 1QP United Kingdom	Moist Heat Sterilization Packaging

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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

**Moist Heat Sterilization
Packaging**

Synergy Health (UK) Ltd
Sterile Services Department, Gate 7
Homerton University Hospital NHS
Homerton Row
Greater London
E9 6SR
United Kingdom

**Moist Heat Sterilization
Packaging**

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Wythenshawe
M23 9GF
United Kingdom

Subcontractor:

Service(s) supplied

Synergy Health (UK) Ltd
Northwick Park &
St Marks Hospital HSDU
Harrow
Middlesex
HA1 3UJ
United Kingdom

Hydrogen peroxide sterilization
Moist Heat Sterilization
Packaging

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

Hydrogen peroxide sterilization
Moist Heat Sterilization
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Wythenshawe
M23 9GF
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
 Epsom SSD, Epsom General Hospital
 Dorking Road
 Epsom
 Surrey
 KT18 7EG
 United Kingdom

**Moist Heat Sterilization
 Packaging**

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Wythenshawe
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

**Moist Heat Sterilization
Packaging**

Synergy Health (UK) Ltd
Units 4-5 Mallard Way
Strathclyde Business Park
Bellshill
Lanarkshire
ML4 3BF
United Kingdom

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Moist Heat Sterilization
Packaging**

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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

**Moist Heat Sterilization
Packaging**

Synergy Health (UK) Ltd
Sterile Services Department
Kingston Hospital NHS Trust
Galsworthy Road
Kingston-upon-Thames
Surrey
KT2 7QB
United Kingdom

**Moist Heat Sterilization
Packaging**

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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.
19 April 2020	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.

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Date	Reference Number	Action
28 September 2020	3257592	Addition of hydrogen peroxide sterilization as an approved activity at Synergy Health (UK) Ltd. (Harrow). Update to activity description for sites conducting sterilization using vaporized hydrogen peroxide (Wolverhampton, Sheffield, Guildford and Bellshill). Activity descriptions are selected from a pre-defined list, now updated to include "Hydrogen Peroxide Sterilization". This term more accurately reflects the activities performed and has replaced "Gas Plasma" which was previously used.
03 December 2020	3299120	Addition of Synergy Health (UK) Ltd subcontractor location in Kingston for moist heat sterilization and packaging.
Current	3313794	Addition of Steris Ireland Limited as an EU representative. Addition of hydrogen peroxide sterilization as an approved activity for Synergy (Royal London) subcontractor location.