

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: **2020-09-28**

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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List of Significant Subcontractors

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

Certificate No: **CE 671655**
Date: **2020-09-28**
Issued To: **Synergy Health (UK) Ltd**
Pegasus House, Tilson Road
Roundthorn Industrial Estate
Wythenshawe
M23 9GF
United Kingdom

Subcontractor:**Service(s) supplied**

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

Synergy Health (UK) Ltd
Sterile Services Department, Royal London Hospital
Stepney Way
Whitechapel
Greater London
E1 1BB
United Kingdom

Moist Heat Sterilization
Packaging

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Wythenshawe
M23 9GF
United Kingdom

Subcontractor:	Service(s) supplied
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
Synergy Health (UK) Ltd Princess Royal University Hospital Sterile Services Farnborough Common Orpington Kent BR6 8ND United Kingdom	Moist Heat Sterilization Packaging

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United Kingdom

Subcontractor:	Service(s) supplied
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
Synergy Health (UK) Ltd Overbrook Lane Knowsley Business Park Knowsley Merseyside L34 9FB United Kingdom	Moist Heat Sterilization Packaging

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Wythenshawe
M23 9GF
United Kingdom

Subcontractor:	Service(s) supplied
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
Synergy Health (UK) Ltd Northwick Park & St Marks Hospital HSDU Harrow Middlesex HA1 3UJ United Kingdom	Hydrogen peroxide sterilization Moist Heat Sterilization Packaging

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United Kingdom

Subcontractor:

Service(s) supplied

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

Hydrogen peroxide sterilization
Moist Heat Sterilization
Packaging

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

Moist Heat Sterilization
Packaging

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United Kingdom

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Epsom SSD, Epsom General Hospital Dorking Road Epsom Surrey KT18 7EG United Kingdom	Moist Heat Sterilization Packaging
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

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Wythenshawe
M23 9GF
United Kingdom

Subcontractor:	Service(s) supplied
Synergy Health (UK) Ltd Units 4-5 Mallard Way Strathclyde Business Park Bellshill Lanarkshire ML4 3BF United Kingdom	Hydrogen peroxide sterilization Moist Heat Sterilization Packaging
Synergy Health (UK) Ltd Tameside General Hospital Fountain Street Ashton-under-Lyne Lancashire OL6 9RW United Kingdom	Moist Heat Sterilization Packaging

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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.
Current	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.

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This certificate was issued electronically and is bound by the conditions of the contract.

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

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A member of BSI Group of Companies.