

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. UKCA 751992
Issued To: Synergy Health (UK) Ltd
Pegasus House
Tilson Road
Roundthorn Industrial Estate
Wythenshawe
M23 9GF
United Kingdom

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility by moist heat and vaporized hydrogen peroxide in the assembly of procedure packs and instrument sets in accordance with Regulation 14 of the UK MDR 2002.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-07-15**

Date: **2021-07-15**

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 regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 751992**
 Date: **2021-07-15**
 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 Units 1-4 Barwell Business Park Leatherhead Road Chessington Surrey KT9 2NY United Kingdom	Hydrogen peroxide sterilization Moist Heat Sterilization Packaging
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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Wythenshawe
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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Tilson Road
Roundthorn Industrial Estate
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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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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Tilson Road
Roundthorn Industrial Estate
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 Packaging

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Pegasus House
Tilson Road
Roundthorn Industrial Estate
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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Tilson Road
Roundthorn Industrial Estate
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	Hydrogen peroxide sterilization Moist Heat Sterilization Packaging

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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

**Moist Heat Sterilization
Packaging**

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Certificate History

Certificate No: **UKCA 751992**
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United Kingdom

Date	Reference Number	Action
Current	3476905	First issue; Traceable to CE 671655. Addition of Synergy Health (UK) Ltd subcontractor location in Chessington for moist heat and hydrogen peroxide sterilization and packaging. Removal of Synergy Health (UK) Ltd subcontractor in Kingston and removal of EU representative.

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