

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: **2021-12-10**

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

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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: **2021-12-10**
 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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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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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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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 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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Tilson Road
Roundthorn Industrial Estate
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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Wythenshawe
M23 9GF
United Kingdom

Subcontractor:

Service(s) supplied

Synergy Health (UK) Ltd
Chesterfield Royal Hospital
NHS Foundation Trust
Decontamination Units
Top Road
Calow
Chesterfield
S44 5BL
United Kingdom

Hydrogen peroxide sterilization
Moist Heat Sterilization
Packaging

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Certificate History

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Date	Reference Number	Action
15 July 2021	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.
Current	3598160	Addition of Synergy Health (UK) Ltd subcontractor location in Chesterfield for moist heat and hydrogen peroxide sterilization and packaging. Removal of Synergy Health (UK) Ltd subcontractor in Epsom.

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