



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. Issued To: UKCA 751992

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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2021-07-15

Date: 2022-12-01

Expiry Date: 2027-12-13

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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.





UKCA Certificate - Production Quality Assurance Certificate History

Certificate No: Date:

Issued To:

UKCA 751992 2022-12-01 Synergy Health (UK) Ltd Pegasus House

Tilson Road Roundthorn Industrial Estate Wythenshawe M23 9GF United Kingdom

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.
10 December 2021	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.
Current	3770286	Certificate renewal.

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