

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):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2021-07-15

Date: 2022-12-01

Expiry Date: 2027-12-13

UKCA Certificate - Production Quality Assurance 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.
10 December 2021	3598160	Addition of Synergy Health (UK) Ltd subcontractor location in Chesterfield for moist heat and hydrogen peroxide sterilization