

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

**STERIS Applied Sterilization
Technologies (Formerly Synergy Health
Applied Sterilization Technologies)**
Moray Road
Elgin Industrial Estate
Swindon
SN2 8XS
United Kingdom

Holds Certificate Number:

MD 77332

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The provision of contract gamma, electron beam and X-Ray irradiation processing services in accordance with EN ISO 11137-1:2015.

The provision of a contract ethylene oxide processing services with associated laboratory testing services in accordance with EN ISO 11135:2014.

The provision of contract washing, packing and moist heat sterilization (LCS) processing services and transport of medical devices in accordance with EN ISO 17665-1:2006.

The provision of consulting, validation, and laboratory testing services including microbiological, biological, chemical and radiometric testing.

The provision of cross-linking modification of polymers and experimental irradiation processes.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-08-13

Latest Revision Date: 2017-04-28

Effective Date: 2015-07-18

Expiry Date: 2018-07-17



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Certificate No: MD 77332

| Location | Registered Activities |
|--|--|
| STERIS Applied Sterilization Technologies Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Reading) Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd (Synergy Health AST South Marston) Thornhill Road South Marston Swindon SN3 4TA United Kingdom | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015 and cross linking modification of polymers. |

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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| Location | Registered Activities |
|--|--|
| Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia | The provision of contract ethylene oxide processing and irradiation services with associated laboratory testing service in accordance with EN ISO 11135:2014 and EN ISO 11137-1:2015. |
| Synergy Health Westport Ltd (Synergy Health - AST - Westport) Lodge Road Westport County Mayo Ireland | The provision of a contract irradiation processing service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland | The provision of contract ethylene oxide and electron beam irradiation processing services with associated laboratory testing services in accordance with EN ISO 11135:2014 and EN ISO 11137-1:2015. |
| Synergy Health AST, Ede Morsestraat 3 Ede 6716 AH The Netherlands | The provision of a contract irradiation processing service with associated laboratory testing services in accordance with EN ISO 11137-1:2015. |
| Synergy Health AST, Etten-Leur Soevereinstraat 2 Etten-Leur 4879 NN The Netherlands | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Marseille (Marseille) MIN 712 - LES Arnavaux MARSEILLE CEDEX 14 13323 France | The provision of a contract irradiation processing service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |

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| Synergy Sterilisation South Africa Proprietary Ltd 5 Waterpas Street Isando Extension 3 Kempton Park 1620 South Africa | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh, Amphur Muang Chonburi, Chonburi 20000 Thailand | The provision of a contract irradiation service utilizing a Pallet and Tote Irradiator in accordance with EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom | The provision of a contract ethylene oxide processing service with associated laboratory testing in accordance with EN ISO 11135:2014. The provision of a microbiological testing and consulting service. |
| Synergy Health AST, Venlo Faunalaan 38 Venlo 5928 RZ The Netherlands | The provision of a contract ethylene oxide processing service in accordance with EN ISO 11135:2014. |
| Synergy Health PL, Utrecht Reactorweg 47A Utrecht 3542 AD The Netherlands | The provision of a chemical laboratory testing service. |
| Synergy Health PL, Ede Morsestraat 3 Ede 6716 AH The Netherlands | The provision of a microbiological laboratory testing service. |

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| Synergy Health Sterilisation UK Ltd (Synergy Health - AST - South Marston Labs) Thornhill Road South Marston Swindon SN3 4TA United Kingdom | The provision of a microbiological testing and consultancy service to the Health Care Industry. |
| Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany | The provision of contract gamma and electron beam irradiation processing, processing services and alanine dosimetry in accordance with EN ISO 11137-1:2015 and associated laboratory testing services. |
| Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia | The provision of contract ethylene oxide processing in accordance with EN ISO 11135:2014. |
| Synergy Sterilisation Rawang (M) Sdn.Bhd Lot 42, Jalan Industri 2/1 Rawang Integrated Industrial Park Selangor, Rawang 48000 Malaysia | The provision of contract irradiation service in accordance with EN ISO 11137-1:2015. |
| Synergy Health Marseille (Marcoule) Lieu dit Combe Bertrand RD 138 CHUSCLAN 30200 France | The provision of a contract irradiation service in accordance with EN ISO 11137-1:2015 and irradiator operation for experimental purposes. |
| Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland | The provision of gamma, electron beam and x-ray processing services in accordance with EN ISO 11137-1:2015 and cross-linking modification of polymers. |

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| Location | Registered Activities |
|--|---|
| STERIS S.p.A. Via Cà Bertoncina, 29 Seriante (BG) 24068 Italy | The provision of contract electron beam irradiation and ethylene oxide processing services in accordance with EN ISO 11137-1:2015 and EN ISO 11135:2014. The provision of contract washing, packing and moist heat sterilization (LCS) processing services in accordance with EN ISO 17665-1:2006. The provision of services including validation studies for treatment processes (electron beam, ethylene oxide, steam and gamma rays); microbiological, chemical and radiometric tests and analysis, validation studies or packaging systems for medical devices and related tests and analysis: validation studies for washing systems for medical devices and related tests and analyses; validation studies of cleanrooms and associated controlled environment and related tests and analysis, transport for medical devices. |
| STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic | The provision of ethylene oxide processing services and associated microbiological, biological, and chemical testing and validation services in accordance with EN ISO 11135:2014. |
| STERIS S.p.A. Via A. Piva snc Poggio Rusco (MN) 46025 Italy | The provision of contract electron beam irradiation and ethylene oxide processing services in accordance with EN ISO 11137-1:2015 and EN ISO 11135:2014. The provision of services including validation studies for treatment processes (electron beam, ethylene oxide, steam and gamma rays); microbiological, chemical and radiometric tests and analysis, validation studies or packaging systems for medical devices and related tests and analysis: validation studies for washing systems for medical devices and related tests and analyses; validation studies of cleanrooms and associated controlled environment and related tests and analysis, transport for medical devices. |
| STERIS S.p.A. Via 1° Maggio,10 Bastia di Rovolon (PD) 35030 Italy | The provision of contract electron beam irradiation processing services in accordance with EN ISO 11137-1:2015. |
| STERIS S.p.A. Via Einaudi, 9 Calcinate (BG) 24050 Italy | The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014. |

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Location

STERIS AST SK s.r.o.
Priemyselny park 6020/5
Michalovce
07101
Slovakia

Registered Activities

The provision of ethylene oxide processing services and associated microbiological, biological, and chemical testing and validation services in accordance with EN ISO 11135:2014.

Synergy Health (Suzhou)
Sterilization Technologies Ltd
No. 26 Xinchang Road
Suzhou Industrial Park
Jiangsu
215125
China

The provision of a contract ethylene oxide processing service with associated laboratory testing in accordance with EN ISO 11135:2014.



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