



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

STERIS Applied Sterilization
Technologies
5960 Heisley Road
Mentor
Ohio
44060
USA

Holds Certificate Number:

MD 741352

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-12-21

Latest Revision Date: 2022-11-04

Effective Date: 2021-07-18

Expiry Date: 2024-07-17

Page: 1 of 8



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Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: **MD 741352**

Registered Scope:

The provision of contract gamma, electron beam and X-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.

The provision of contract vaporised hydrogen peroxide sterilization services.

The provision of distribution services for the purpose of medical device storage.

The provision of laboratory testing services.

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

The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

The provision of validation studies of cleanrooms, associated controlled environments and related tests and analyses.



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Page: 2 of 8

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Certificate No: **MD 741352**

Location	Registered Activities
Synergy Health Sterilisation UK Ltd Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Sterilisation UK Ltd Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Sterilisation UK Ltd Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	The provision of contract gamma and electron beam irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	The provision of contract ethylene oxide, gamma and x-ray sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and EN ISO 11137-1:2015.
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

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Page: 3 of 8

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Location	Registered Activities
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	The provision of contract ethylene oxide and electron beam sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and EN ISO 11137-1:2015. The provision of contract vaporised hydrogen peroxide sterilization services.
Synergy Health Ede BV Morsestraat 3 Ede 6716 AH The Netherlands	The provision of a contract gamma irradiation sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Ede BV Soeverinstraat 2 Etten-Leur 4879 NN The Netherlands	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Marseille - SAS Site de Marseille MIN 712 - LES Arnavaux MARSEILLE CEDEX 14 13323 France	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Sterilisation South Africa Proprietary Ltd 5 Waterpas Street Isando Extension 3 Kempton Park 1620 South Africa	The provision of a contract gamma irradiation sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

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Page: 4 of 8

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Location	Registered Activities
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh Amphur Muang Chonburi Chonburi 20000 Thailand	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	The provision of a contract ethylene oxide sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Synergy Health Ede BV Faunalaan 38 Venlo 5928 RZ The Netherlands	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Synergy Health Sterilization UK Ltd Thornhill Road South Marston Swindon, Wiltshire SN3 4TA United Kingdom	The provision of laboratory testing services.
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	The provision of contract gamma and electron beam irradiation sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.

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Page: 5 of 8

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Location	Registered Activities
Synergy Sterilisation Rawang (M) Sdn. Bhd. Lot 42, Jalan Industri 2/1 Rawang Integrated Industrial Park Rawang Selangor 48000 Malaysia	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Marseille - SAS Site de Marcoule Lieu dit Combe Bertrand RD 138 CHUSCLAN 30200 France	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	The provision of contract gamma, electron beam and X-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015 and cross-linking modification of polymers.
STERIS S.p.A. Via Cà Bertoncina, 29 Seriate (BG) 24068 Italy	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. The provision of laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015 and EN ISO 11135:2014. The provision of validation studies of cleanrooms, associated controlled environments and related tests and analyses.
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	The provision of a contract ethylene oxide sterilization service with associated testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
STERIS S.p.A. Via A. Piva snc Poggio Rusco (MN) 46025 Italy	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

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Page: 6 of 8

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Location	Registered Activities
STERIS S.p.A. Via Einaudi, 9 Calcinate (BG) 24050 Italy	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.
STERIS Sterilization Technologies (Suzhou) Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	The provision of a contract ethylene oxide sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
STERIS AST d.o.o Pod gabri 18, PC Zeje pri Komendi 1218 Komenda Slovenia	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. The provision of distribution services for the purposes of medical device storage.
Herotron E-Beam Service GmbH Guardianstr. 6-10 06766 Bitterfeld-Wolfen Germany	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. The provision of cross-linking modification of polymers and experimental irradiation processes.
STERIS Applied Sterilization Technologies 5960 Heisley Road Mentor Ohio 44060 USA	Group Level Headquarters.
STERIS TOMOE (Thailand) Ltd. 700/644 Moo 3 Tambon Bankao Amphur Panthong Chonburi 20160 Thailand	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

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Page: 7 of 8

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Location	Registered Activities
Electron Beam Sdn. Bhd. Lot 7, Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (Fasa 2) Port Klang Selangor Darul Ehsan 42920 Malaysia	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health Ede BV Faunalaan 46 Venlo 5928 RZ The Netherlands	The provision of a contract x-ray irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.



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Supplementary Information

Certificate Number: MD 741352
Date: 2022-11-04
Issued to: STERIS Applied Sterilization Technologies
5960 Heisley Road
Mentor
Ohio
44060
USA

The holder of the ISO13485 certificate referenced above provides sterilisation services at some or all of the certified locations.

Assessments to achieve and maintain certification at the certified locations are conducted by qualified BSI microbiologists. These assessments include verification that the quality system complies with the full requirements of applicable harmonised sterilisation standards relevant to health care products.

The information provided in this document summarises the harmonised sterilisation standards implemented within the quality system at each certified location. All certified locations have been assessed and found to comply with the full requirements of the harmonised standards specified in the table below.

BSI Assurance UK Limited, BSI The Netherlands B.V. and BSI Americas Inc. apply identical processes for the audit and ISO13485 certification of sterilisation service providers, including certification scheme and competency requirements. Audits are conducted by technical specialists qualified in the field of microbiology.

Should you have any questions regarding the information included in this document, please contact me or BSI's dedicated certificate verification team at Certificate.Verification@bsigroup.com.

Alena Solowiej

Alena Solowiej
Certification Specialist, Medical Devices
alena.solowiej@bsigroup.com

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-051	STERIS Applied Sterilization Technologies 5960 Heisley Road Mentor Ohio 44060 USA	None
ISOTRO-0008903820-000	Synergy Health Sterilisation UK Ltd Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	EN ISO 11137-1:2015
ISOTRO-0008903820-001	Synergy Health Sterilisation UK Ltd Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	EN ISO 11137-1:2015
ISOTRO-0008903820-002	Synergy Health Sterilisation UK Ltd Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-003	Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	EN ISO 11137-1:2015
ISOTRO-0008903820-005	Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	EN ISO 11135:2014 EN ISO 11137-1:2015
ISOTRO-0008903820-006	Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	EN ISO 11137-1:2015
ISOTRO-0008903820-007	Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	EN ISO 11135:2014 EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-009	Synergy Health Ede BV Morsestraat 3 Ede 6716 AH The Netherlands	EN ISO 11137-1:2015
ISOTRO-0008903820-010	Synergy Health Ede BV Soeverinstraat 2 Etten-Leur 4879 NN The Netherlands	EN ISO 11137-1:2015
ISOTRO-0008903820-011	Synergy Health Marseille - SAS Site de Marseille MIN 712 - LES Arnavaux MARSEILLE CEDEX 14 13323 France	EN ISO 11137-1:2015
ISOTRO-0008903820-012	Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-013	Synergy Sterilisation South Africa Proprietary Ltd 5 Waterpas Street Isando Extension 3 Kempton Park 1620 South Africa	EN ISO 11137-1:2015
ISOTRO-0008903820-014	Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh Amphur Muang Chonburi Chonburi 20000 Thailand	EN ISO 11137-1:2015
ISOTRO-0008903820-016	Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	EN ISO 11135:2014
ISOTRO-0008903820-017	Synergy Health Ede BV Faunalaan 38 Venlo 5928 RZ The Netherlands	EN ISO 11135:2014

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-021	Synergy Health Sterilization UK Ltd Thornhill Road South Marston Swindon, Wiltshire SN3 4TA United Kingdom	None
ISOTRO-0008903820-022	Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	EN ISO 11137-1:2015
ISOTRO-0008903820-032	Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	EN ISO 11135:2014
ISOTRO-0008903820-033	Synergy Sterilisation Rawang (M) Sdn. Bhd. Lot 42, Jalan Industri 2/1 Rawang Integrated Industrial Park Rawang Selangor 48000 Malaysia	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-034	Synergy Health Marseille - SAS Site de Marcoule Lieu dit Combe Bertrand RD 138 CHUSCLAN 30200 France	EN ISO 11137-1:2015
ISOTRO-0008903820-035	Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	EN ISO 11137-1:2015
ISOTRO-0008903820-039	STERIS S.p.A. Via Cà Bertoncina, 29 Seriante (BG) 24068 Italy	EN ISO 11137-1:2015 EN ISO 11135:2014
ISOTRO-0008903820-040	STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	EN ISO 11135:2014

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-041	STERIS S.p.A. Via A. Piva snc Poggio Rusco (MN) 46025 Italy	EN ISO 11137-1:2015
ISOTRO-0008903820-044	STERIS S.p.A. Via Einaudi, 9 Calcinate (BG) 24050 Italy	EN ISO 11135:2014
ISOTRO-0008903820-046	STERIS Sterilization Technologies (Suzhou) Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	EN ISO 11135:2014
ISOTRO-0008903820-047	STERIS AST d.o.o Pod gabri 18, PC Zeje pri Komendi 1218 Komenda Slovenia	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
ISOTRO-0008903820-050	Herotron E-Beam Service GmbH Guardianstr. 6-10 06766 Bitterfeld-Wolfen Germany	EN ISO 11137-1:2015
ISOTRO-0008903820-052	STERIS TOMOE (Thailand) Ltd. 700/644 Moo 3 Tambon Bankao Amphur Panthong Chonburi 20160 Thailand	EN ISO 11137-1:2015
ISOTRO-0008903820-053	Electron Beam Sdn. Bhd. Lot 7, Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (Fasa 2) Port Klang Selangor Darul Ehsan 42920 Malaysia	EN ISO 11137-1:2015
ISOTRO-0008903820-054	Synergy Health Ede BV Faunalaan 46 Venlo 5928 RZ The Netherlands	EN ISO 11137-1:2015