

Certificate of Registration

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

This is to certify that:

STERIS Applied Sterilization Technologie
Formerly Synergy Health Applied Steriliz
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 13485:2016 & EN ISO 13485:2016 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: 2018-07-16

Effective Date: 2018-07-18

Expiry Date: 2021-07-17

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Certificate No: **MD 77332**

Location	Registered Activities
Synergy Health Sterilisation UK Ltd 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.

Original Registration Date: 2003-08-13

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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 - Groupe Steris Site de 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 processing service with associated laboratory testing services 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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Location	Registered Activities
AST Synergy Health now part of Steris Thornhill Road South Marston Swindon, Wiltshire 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 - Groupe Steris Site de 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 Seriato (BG) 24068 Italy	The provision of contract electron beam irradiation processing services in accordance with EN ISO 11137-1:2015. The provision of services including validation studies for treatment processes electron beam and gamma rays according to EN ISO 11137:2015, ethylene oxide according to EN ISO 11135:2014 and steam according to EN ISO 17665-1:2006; 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.
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.
STERIS S.p.A. Via Einaudi, 9 Calcinato (BG) 24050 Italy	The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.
STERIS AST SK s.r.o. Priemyselny park 6020/5 Michalovce 07101 Slovakia	The provision of ethylene oxide processing services and associated microbiological, biological, and chemical testing and validation services in accordance with EN ISO 11135:2014.

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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.
STERIS AST d.o.o Pod gabri 18, PC Zeje pri Komendi 1218 Komenda Slovenia	The provision of a contract electron beam irradiation service in accordance with EN ISO 11137-1:2015.



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