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 77332

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 Global Regulatory & Quality

Original Registration Date: 2003-08-13
Effective Date: 2024-07-18
Latest Revision Date: 2026-04-30
Expiry Date: 2027-07-17

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BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 77332

Registered Scope:

The provision of contract gamma, electron beam and x-ray irradiation processing services in accordance with ISO 11137-1:2025.
The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.
The provision of contract vaporised hydrogen peroxide sterilization services in accordance with ISO 22441:2022.
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 in accordance with ISO 11137-1:2025.
The provision of validation studies of cleanrooms, associated controlled environments and related tests and analyses.

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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 service in accordance with ISO 11137-1:2025.
Synergy Health Sterilisation UK Ltd Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025. The provision of irradiation for testing gamma to customer requirements in accordance with ISO 11137-1:2025.
Synergy Health Sterilisation UK Ltd Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025.
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	The provision of a contract gamma and electron beam irradiation service in accordance with ISO 11137-1:2025.
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 processing services with associated laboratory testing services in accordance with EN ISO 11135:2014 and ISO 11137-1:2025.
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025.

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Location	Registered Activities
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly R35 X865 Ireland	The provision of contract ethylene oxide and electron beam irradiation services with associated laboratory testing services in accordance with EN ISO 11135:2014 and ISO 11137-1:2025. The provision of contract vaporised hydrogen peroxide sterilization services in accordance with ISO 22441:2022.
Synergy Health Ede BV Morsestraat 3 Ede 6716 AH The Netherlands	The provision of a contract gamma irradiation service with associated laboratory testing services in accordance with ISO 11137-1:2025.
Synergy Health Ede BV Soevereinstraat 2 Etten-Leur 4879 NN The Netherlands	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025.
Synergy Health Marseille - SAS Site de Marseille MIN 712 - LES Arnavaux MARSEILLE CEDEX 14 13323 France	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025.
Synergy Health Allershausen GmbH Kesselbodenstrasse 7 Allershausen D-85391 Germany	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025.
Synergy Sterilisation South Africa Proprietary Ltd 5 Waterpas Street Isando Extension 3 Kempton Park 1620 South Africa	The provision of a contract gamma irradiation service with associated laboratory testing services in accordance with ISO 11137-1:2025.

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Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh Amphur Muang Chonburi Chonburi 20000 Thailand	The provision of contract gamma and x-ray irradiation services in accordance with ISO 11137-1:2025.
Synergy Health Sterilisation UK Ltd 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.
Synergy Health Ede BV 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 Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	The provision of contract gamma and electron beam irradiation services with associated laboratory testing services in accordance with ISO 11137-1:2025.
Synergy Sterilisation Rawang (M) Sdn. Bhd. Lot 42, Jalan Industri 2/1 Rawang Integrated Industrial Park Rawang Selangor 48000 Malaysia	The provision of contract gamma irradiation service in accordance with ISO 11137-1:2025.
Synergy Health Marseille - SAS Site de Marcoule Lieu dit Combe Bertrand RD 138 CHUSCLAN 30200 France	The provision of a contract gamma irradiation service in accordance with ISO 11137-1:2025. The provision of irradiation for testing gamma to customer requirements in accordance with ISO 11137-1:2025.

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Location	Registered Activities
STERIS Schweiz AG Walkistrasse 1 Däniken CH-4658 Switzerland	The provision of gamma and x-ray irradiation services in accordance with ISO 11137-1:2025 and cross-linking modification of polymers.
STERIS S.p.A. Via Cà Bertoncina, 29 Seriate (BG) 24068 Italy	The provision of contract electron beam irradiation services in accordance with ISO 11137-1:2025. The provision of laboratory testing services in accordance with ISO 11137-1:2025 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 contract ethylene oxide processing services with associated testing services in accordance with ISO 11137-1:2025.
STERIS S.p.A. Via Einaudi, 3, 5, 7, 9 Calcinate (BG) 24050 Italy	The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.
STERIS Sterilization Technologies (Suzhou) Ltd No. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	The provision of contract ethylene oxide and x-ray processing services with associated laboratory testing in accordance with EN ISO 11135:2014 and ISO 11137-1:2025.
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 ISO 11137-1:2025. 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 contract electron beam irradiation services in accordance with ISO 11137-1:2025. The provision of cross-linking modification of polymers and experimental irradiation processes.

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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 service in accordance with ISO 11137-1:2025.
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 service in accordance with ISO 11137-1:2025.
Synergy Health Ede BV Faunalaan 46 Venlo 5928 RZ The Netherlands	The provision of a contract x-ray irradiation service in accordance with ISO 11137-1:2025.
STERIS S.p.A. Biassono (Monza) Via Parco, 47 Biassono (MB) 20853 Italy	The provision of a contract electron beam irradiation service in accordance with ISO 11137-1:2025.
Synergy Sterilisation Kulim (M) Sdn.Bhd Plot 329F, Jalan Cassia Selatan 6/4 Kawasan Perindustrian Batu Kawan Seberang Perai Selatan Pulau Pinang 14110 Malaysia	The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.

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Location	Registered Activities
STERIS TOMOE SINGAPORE PTE. LTD. No. 47 Jalan Buroh Unit #01-01 619491 Singapore	The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.

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