

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 89745

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: 2004-10-13

Latest Revision Date: 2024-03-07

Effective Date: 2024-03-13

Expiry Date: 2027-03-12

Page: 1 of 7



...making excellence a habit.™

Certificate No: MD 89745

Registered Scope:

The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.

The provision of contract gamma, electron beam and x-ray irradiation sterilization service in accordance with EN ISO 11137-1:2015.

The provision of a contract moist heat sterilization service in accordance with EN ISO 17665:2024.

The provision of a laboratory testing service for the testing of biological indicators.

The provision of irradiation for testing gamma, e-beam and x-ray to customer requirements in accordance with EN ISO 11137-1:2015.



Original Registration Date: 2004-10-13

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Page: 2 of 7

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

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 89745

Location	Registered Activities
STERIS Applied Sterilization Technologies 5960 Heisley Road Mentor Ohio 44060 USA	Group Level Headquarters.
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	The provision of contract gamma irradiation sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
Isomedix Operations, Inc. 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014. The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.

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Page: 3 of 7

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Location	Registered Activities
Isomedix Operations, Inc. 4405 Marketing Place Groveport Ohio 43125 USA	The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	The provision of contract gamma and x-ray irradiation sterilization service in accordance with EN ISO 11137-1:2015. The provision of irradiation for testing gamma, e-beam and x-ray to customer requirements in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014. The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	The provision of contract gamma and electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.

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Page: 4 of 7

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Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014. The provision of a contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
STERIS Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
STERIS Applied Sterilization Technologies ULC 184 Crown Court Whitby Ontario L1N 7B1 Canada	The provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015.
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	The provision of a contract gamma sterilization service in accordance with EN ISO 11137-1:2015.

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Page: 5 of 7

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Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014.
Synergy Health AST, LLC 9020 Activity Road Suite D San Diego California 92126 USA	The provision of contract electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015.
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	The provision of contract electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015.
Synergy Health AST, SRL B16, Street 4, Avenue 0 Coyol Free Zone Coyol Alajuela 20102 Costa Rica	The provision of contract electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015.
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 Coyol Free Zone Coyol Alajuela 20102 Costa Rica	The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135:2014. The provision of a laboratory testing service for the testing of biological indicators.
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	The provision of contract electron beam sterilization service in accordance with EN ISO 11137-1:2015.

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Page: 6 of 7

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Location

Isomedix Operations, Inc.
2 Nucifora Boulevard
Chester
New York
10918
USA

Registered Activities

The provision of a contract electron beam and x-ray sterilization services in accordance with EN ISO 11137-1:2015.

STERIS Laboratories, Inc.
9303 West Broadway Ave.
Brooklyn Park
Minnesota
55445
USA

The provision of a contract moist heat sterilization service in accordance with EN ISO 17665:2024.



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