

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 741274

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

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

The provision of microbiological laboratory testing services associated with contract sterilization.

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



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-12-21

Latest Revision Date: 2021-03-11

Effective Date: 2021-03-13

Expiry Date: 2024-03-12

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...making excellence a habit.™

Certificate No: **MD 741274**

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 a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015 with associated laboratory testing services.
Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Isomedix Operations, Inc. 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within 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 fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014. The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2020-12-21

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 741274**

Location	Registered Activities
Isomedix Operations, Inc. 4405 Marketing Place Groveport Ohio 43125 USA	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	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, e-beam and x-ray to customer requirements fulfilling applicable quality management system requirements within 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 fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014. The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within 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 services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	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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Location	Registered Activities
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014. The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within 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 fulfilling applicable quality management system requirements within 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 a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
STERIS Applied Sterilization Technologies ULC 184 Crown Court Whitby Ontario L1N 7B1 Canada	The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	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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Location	Registered Activities
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Synergy Health AST, LLC 9020 Activity Road Suite D San Diego California 92126 USA	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health AST, SRL B16, Street 4, Avenue O El Coyo Free Zone El Coyo Alajuela 20102 Costa Rica	The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyo Free Zone El Coyo Alajuela 20102 Costa Rica	The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within 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 a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

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Certificate No: **MD 741274**

Location

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

Registered Activities

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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Supplementary Information

Certificate Number: MD 741274
Date: 2021-03-11
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.



Rebecca Colby
Certification Specialist, Medical Devices
rebecca.colby@bsigroup.com

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-000	STERIS Applied Sterilization Technologies 5960 Heisley Road Mentor Ohio 44060 USA	None
STERIS-0047245776-001	Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	EN ISO 11137-1:2015
STERIS-0047245776-002	Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	EN ISO 11135:2014
STERIS-0047245776-004	Isomedix Operations, Inc. 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	EN ISO 11135:2014

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-005	Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	EN ISO 11135:2014
STERIS-0047245776-006	Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	EN ISO 11135:2014 EN ISO 11137-1:2015
STERIS-0047245776-007	Isomedix Operations, Inc. 4405 Marketing Place Groveport Ohio 43125 USA	EN ISO 11137-1:2015
STERIS-0047245776-008	Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-009	Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	EN ISO 11135:2014
STERIS-0047245776-011	Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	EN ISO 11135:2014 EN ISO 11137-1:2015
STERIS-0047245776-012	Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	EN ISO 11137-1:2015
STERIS-0047245776-013	Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-015	Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	EN ISO 11135:2014 EN ISO 11137-1:2015
STERIS-0047245776-016	Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	EN ISO 11135:2014
STERIS-0047245776-017	STERIS Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	EN ISO 11137-1:2015
STERIS-0047245776-018	Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-019	STERIS Applied Sterilization Technologies ULC 184 Crown Court Whitby Ontario L1N 7B1 Canada	EN ISO 11137-1:2015
STERIS-0047245776-020	Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	EN ISO 11137-1:2015
STERIS-0047245776-022	Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	EN ISO 11135:2014
STERIS-0047245776-023	Synergy Health AST, LLC 9020 Activity Road Suite D San Diego California 92126 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-026	Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	EN ISO 11137-1:2015
STERIS-0047245776-027	Synergy Health AST, SRL B16, Street 4, Avenue O El Coyoil Free Zone El Coyoil Alajuela 20102 Costa Rica	EN ISO 11137-1:2015
STERIS-0047245776-028	Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyoil Free Zone El Coyoil Alajuela 20102 Costa Rica	EN ISO 11135:2014
STERIS-0047245776-029	Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
STERIS-0047245776-030	Isomedix Operations, Inc. 2 Nucifora Boulevard Chester New York 10918 USA	EN ISO 11137-1:2015