

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:

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

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



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-10-13

Latest Revision Date: 2020-12-08

Effective Date: 2018-03-13

Expiry Date: 2021-03-12

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...making excellence a habit.™

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 a contract gamma irradiation sterilization service in accordance with 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 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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| 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 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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| Location | Registered Activities |
|--|---|
| 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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| Location | Registered Activities |
|--|--|
| 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 O El Coyol Free Zone El 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 El Coyol Free Zone El 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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Location

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

Registered Activities

The provision of a contract electron beam sterilization service
in accordance with EN ISO 11137-1:2015.

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