

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

STERIS Applied Sterilization Technologies
(Formerly STERIS Isomedix Services)
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 13485:2003 & EN ISO 13485:2012 for the following scope:

The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007.
The provision of contract gamma and electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 13/10/2004

Latest Revision Date: 04/11/2016

Effective Date: 13/03/2015

Expiry Date: 12/03/2018

Page: 1 of 5



...making excellence a habit.™

Certificate No: MD 89745

| Location | Registered Activities |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| STERIS Applied Sterilization Technologies (Formerly STERIS Isomedix Services) 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 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 11135-1:2007. |
| 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 11135-1:2007. |
| STERIS Isomedix Services Inc 7685 Saint Andrews Avenue San Diego California 92154 USA | The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007. |
| 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 11135-1:2007. The provision of contract irradiation sterilization service in accordance with EN ISO 11137-1:2015. |

Original Registration Date: 13/10/2004

Effective Date: 13/03/2015

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Page: 2 of 5

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An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 89745

| Location | Registered Activities |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Isomedix Operations, Inc. 4405 Marketing Place Groveport Ohio 43125 USA | The provision of contract irradiation 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. |
| 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 11135-1:2007. |
| Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA | The provision of a contract ethylene oxide sterilization service in accordance with EN ISO 11135-1:2007. The provision of contract irradiation 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 irradiation sterilization service in accordance with EN ISO 11137-1:2015. |

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Page: 3 of 5

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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 11135-1:2007. The provision of a contract irradiation 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 11135-1:2007. |
| Isomedix (Puerto Rico) Inc. State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico | The provision of contract irradiation 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 irradiation sterilization service in accordance with EN ISO 11137-1:2015. |
| Isomedix Corporation (Canada) 184 Crown Court Whitby Ontario L1N 7B1 Canada | The provision of contract irradiation 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 irradiation sterilization service in accordance with EN ISO 11137-1:2015. |

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Page: 4 of 5

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Location

Isomedix Operations, Inc.
1441 Don Haskins Drive
El Paso
Texas
79936
USA

Registered Activities

The provision of a contract ethylene oxide sterilization service
in accordance with EN ISO 11135-1:2007.



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