

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Sotera Health LLC
2015 Spring Road
Suite 650
Oak Brook
Illinois
60523
USA

Holds Certificate Number:

MD 741791

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 ethylene oxide and radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 & EN ISO 11137-1:2015.

Chemistry, microbiology and consulting services for the sterilization industry.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-02-09

Latest Revision Date: 2023-04-26

Effective Date: 2021-03-27

Expiry Date: 2024-03-26

Page: 1 of 8



...making excellence a habit.™

Certificate No: **MD 741791**

Location	Registered Activities
Sotera Health LLC 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	The provision of ethylene oxide and radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 & EN ISO 11137-1:2015. Chemistry, microbiology, consulting and associated laboratory services for the sterilization industry.
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	The provision of ethylene oxide sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11135:2014. Chemistry, microbiology and associated laboratory services for the sterilization industry.
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.

Original Registration Date: 2021-02-09

Effective Date: 2021-03-27

Latest Revision Date: 2023-04-26

Expiry Date: 2024-03-26

Page: 2 of 8

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 741791**

Location	Registered Activities
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 344 Bonnie Circle Corona California 92878 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 711 East Cooper Court Schaumburg Illinois 60173 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2021-02-09

Effective Date: 2021-03-27

Latest Revision Date: 2023-04-26

Expiry Date: 2024-03-26

Page: 3 of 8

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 741791**

Location	Registered Activities
Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 1401 Morgan Circle Tustin California 92780 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 75 Tilbury Road Salem New Jersey 08079 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2021-02-09

Effective Date: 2021-03-27

Latest Revision Date: 2023-04-26

Expiry Date: 2024-03-26

Page: 4 of 8

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 741791**

Location	Registered Activities
Sterigenics US, LLC 5900 Obata Way, Suite A Gilroy California 95020 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015
Sterigenics US, LLC 108 Lake Denmark Road Rockaway New Jersey 07866 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	The provision of electron beam radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics S.de R.L de C.V. Calle Norte 7 s/n Parque Industrial Tepeji Tepeji del Rio de Ocampos Edo. de Hidalgo CP 42850 Mexico	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics (Thailand) Ltd. 109/16 Eastern Seaboard Industrial Estate (Rayong), Moo 4 T. Pluakdaeng A. Pluakdaeng, Rayong Province 21140 Thailand	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2021-02-09

Latest Revision Date: 2023-04-26

Effective Date: 2021-03-27

Expiry Date: 2024-03-26

Page: 5 of 8

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 741791**

Location	Registered Activities
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics Shanghai ETO Ltd. No. 333, Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics Shanghai E Beam Ltd. A603 Lane 108 No. 588, Chuantu Road, Chuan Sha, Pudong Shanghai 201202 China	The provision of electron beam irradiation sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. Chemistry, microbiology and associated laboratory services for the sterilization industry.
Sterigenics Belgium (Fleurus) SA Zoning Industriel de Fleurus Avenue De L'Esperance 17 Fleurus, Hainaut B-6220 Belgium	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	The provision of ethylene oxide sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11135:2014. Chemistry, microbiology and associated laboratory services for the sterilization industry.
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	The provision of ethylene oxide sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11135:2014. Chemistry, microbiology and associated laboratory services for the sterilization industry.

Original Registration Date: 2021-02-09

Latest Revision Date: 2023-04-26

Effective Date: 2021-03-27

Expiry Date: 2024-03-26

Page: 6 of 8

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 741791**

Location	Registered Activities
Sterigenics Denmark A/S Aa Louis-Hansens Alle 11 Espergaerde, Region Sjælland DK-3060 Denmark	The provision of electron beam irradiation sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. Chemistry, microbiology and associated laboratory services for the sterilization industry.
Sterigenics SAS 8 Rue Parmentier Rantigny 60290 France	The provision of ethylene oxide sterilization services and associated laboratory services fulfilling applicable quality management system requirements within EN ISO 11135:2014. Chemistry, microbiology and associated laboratory services for the sterilization industry.
Sterigenics Costa Rica S.R.L. Zona Franca PROPARK Calle Principal, Edificio 10 El Coyol Alajuela 20101 Costa Rica	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics S.de R.L de C.V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Edo. de Mexico CP 54730 Mexico	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics US, LLC 502 Prairie Mine Road Mulberry Florida 33860 USA	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2021-02-09

Latest Revision Date: 2023-04-26

Effective Date: 2021-03-27

Expiry Date: 2024-03-26

Page: 7 of 8

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 741791**

Location	Registered Activities
Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015
Sterigenics Italy Spa via Marzabotto, 4 Minerbio Bologna 40061 Italy	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics EO Canada, Inc. 400 Ambassador Dr. Mississauga Toronto Ontario L5T 2J3 Canada	The provision of ethylene oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014.
Sterigenics Jarinu SP Brasil Avenida do Progresso, 900 Ponte Alta Jarinu São Paulo 13240-00 Brasil	The provision of gamma and electron beam radiation services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Sterigenics Cotia SP Brasil Av. Cruzada Banadeirantes, 290 Vila Jovina Cotia São Paulo 06705-140 Brasil	The provision of gamma radiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

Original Registration Date: 2021-02-09

Latest Revision Date: 2023-04-26

Effective Date: 2021-03-27

Expiry Date: 2024-03-26

Page: 8 of 8

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.