

Supplementary Information

Certificate Number: MD 741791
Date: 2021-03-26
Issued to: Sotera Health LLC
2015 Spring Road
Suite 650
Oak Brook
Illinois
60523
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.

K Armoogum

Kevin Armoogum
Certification Specialist, Medical Devices
kevin.armoogum@bsigroup.com

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-000	Sotera Health LLC 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	None
GRIFFI-0009251978-002	Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	EN ISO 11135:2014
GRIFFI-0009251978-003	Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	EN ISO 11135:2014
GRIFFI-0009251978-005	Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-006	Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	EN ISO 11135:2014
GRIFFI-0009251978-007	Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	EN ISO 11135:2014
GRIFFI-0009251978-008	Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	EN ISO 11135:2014
GRIFFI-0009251978-009	Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	EN ISO 11135:2014

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-010	Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	EN ISO 11135:2014
GRIFFI-0009251978-011	Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	EN ISO 11135:2014
GRIFFI-0009251978-013	Sterigenics US, LLC 344 Bonnie Circle Corona California 92878 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-014	Sterigenics US, LLC 711 East Cooper Court Schaumburg Illinois 60173 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-015	Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-016	Sterigenics US, LLC 1401 Morgan Circle Tustin California 92780 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-017	Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-018	Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-019	Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-020	Sterigenics US, LLC 75 Tilbury Road Salem New Jersey 08079 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-021	Sterigenics US, LLC 5900 Obata Way, Suite A Gilroy California 95020 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-022	Sterigenics US, LLC 108 Lake Denmark Road Rockaway New Jersey 07866 USA	EN ISO 11137-1:2015

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GRIFFI-0009251978-023	Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-024	Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-026	Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario M1L3K2 Canada	EN ISO 11135:2014
GRIFFI-0009251978-028	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	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-029	Sterigenics (Thailand) Ltd. 109/16 Eastern Seaboard Industrial Estate (Rayong), Moo 4 T. Pluakdaeng A. Pluakdaeng, Rayong Province 21140 Thailand	EN ISO 11137-1:2015
GRIFFI-0009251978-031	Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-032	Sterigenics Shanghai ETO Ltd. No. 333, Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	EN ISO 11135:2014
GRIFFI-0009251978-033	Sterigenics Shanghai E Beam Ltd. A603 Lane 108 No. 588, Chuantu Road, Chuan Sha, Pudong Shanghai 201202 China	EN ISO 11137-1:2015

Certified Locations

BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-034	Sterigenics Belgium (Fleurus) SA Zoning Industriel de Fleurus Avenue De L'Esperance 17 Fleurus, Hainaut B-6220 Belgium	EN ISO 11137-1:2015
GRIFFI-0009251978-035	Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	EN ISO 11135:2014
GRIFFI-0009251978-037	Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit- Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	EN ISO 11135:2014
GRIFFI-0009251978-038	Sterigenics Denmark A/S Aa Louis-Hansens Alle 11 Espergaerde, Region Sjaelland DK-3060 Denmark	EN ISO 11137-1:2015

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GRIFFI-0009251978-039	Sterigenics SAS 8 Rue Parmentier Rantigny 60290 France	EN ISO 11135:2014
GRIFFI-0009251978-042	Sterigenics Costa Rica S.R.L. Zona Franca PROPARK Calle Principal, Edificio 10 El Coyol Alajuela 20101 Costa Rica	EN ISO 11135:2014
GRIFFI-0009251978-043	Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	EN ISO 11135:2014
GRIFFI-0009251978-044	Sterigenics S.de R.L de C.V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Edo. de Mexico CP 54730 Mexico	EN ISO 11135:2014

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BSI Location Reference	Location Name and Full Address	Sterilisation Standards
GRIFFI-0009251978-046	Sterigenics US, LLC 502 Prairie Mine Road Mulberry Florida 33860 USA	EN ISO 11137-1:2015
GRIFFI-0009251978-048	Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	EN ISO 11137-1:2015