

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SeraCare Life Sciences, Inc.
37 Birch Street
Milford
Massachusetts
01757
USA

Holds Certificate No:

FM 572228

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-04-11

Latest Revision Date: 2018-12-21

Effective Date: 2019-01-01

Expiry Date: 2020-10-02

Page: 1 of 4



...making excellence a habit.™

Certificate No: **FM 572228**

Registered Scope:

The design, development, manufacture and distribution of research and in vitro diagnostic reagents.

The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents.

The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries.

The repackaging, relabeling and distribution of human and animal powders and solutions used in the research and diagnostic industries.



Original Registration Date: 2011-04-11

Latest Revision Date: 2018-12-21

Effective Date: 2019-01-01

Expiry Date: 2020-10-02

Page: 2 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **FM 572228**

Location	Registered Activities
SeraCare Life Sciences, Inc. 25 Birch Street Milford Massachusetts 01757 USA	<p>The design, development, manufacture and distribution of research and in vitro diagnostic reagents.</p> <p>The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents.</p> <p>The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries.</p> <p>The repackaging, relabeling and distribution of human and animal powders and solutions used in the research and diagnostic industries.</p>
SeraCare Life Sciences, Inc. 37 Birch Street Milford Massachusetts 01757 USA	<p>The design, development, manufacture and distribution of research and in vitro diagnostic reagents.</p> <p>The design, development, manufacture and distribution of in vitro diagnostic reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents.</p> <p>The design development, manufacture and distribution of bulk serum and plasma, specialty biologics, and detection system products used in the research and diagnostic industries.</p> <p>The repackaging, relabeling and distribution of human and animal powders and solutions used in the research and diagnostic industries.</p>

Original Registration Date: 2011-04-11

Effective Date: 2019-01-01

Latest Revision Date: 2018-12-21

Expiry Date: 2020-10-02

Page: 3 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 572228**

Location

SeraCare Life Sciences, Inc.
910 Clopper Road
Gaithersburg
Maryland
20878
USA

Registered Activities

The design, development, manufacture and distribution of research reagents.

The design, development, manufacture and distribution of research reagents and kits, quality control products, and clinical services used in the diagnosis and management of blood analytes, blood components, cancer, disease status, donor screening, endocrine disorders, genetic testing, immune status, prenatal screening, protein metabolism, sexually transmissible agents and transmissible agents.



Original Registration Date: 2011-04-11

Latest Revision Date: 2018-12-21

Effective Date: 2019-01-01

Expiry Date: 2020-10-02

Page: 4 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.