



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 04/11/2011

Effective Date: 12/04/2014

Expiry Date: 10/05/2017



CMDCAS  
Recognized  
Registrar



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.

This certificate is traceable to this company's original registration certificate number 9270 dated November 21, 2008 and issued by LNE.



Originally registered: 04/11/2011

Effective Date: 12/04/2014

Expiry Date: 10/05/2017

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](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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>

Originally registered: 04/11/2011

Effective Date: 12/04/2014

Expiry Date: 10/05/2017

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](http://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.



Originally registered: 04/11/2011

Effective Date: 12/04/2014

Expiry Date: 10/05/2017

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](http://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.