

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LGC Clinical Diagnostics, Inc.

37 Birch Street
Milford
Massachusetts
01757
USA

Holds Certificate Number:

FM 572228

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2011-04-11

Latest Revision Date: 2024-10-04

Effective Date: 2024-10-03

Expiry Date: 2027-10-02

Page: 1 of 2



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Certificate No: FM 572228

Location	Registered Activities
LGC Clinical Diagnostics, 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>
LGC Clinical Diagnostics, 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>

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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

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