

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:

Design, development and manufacture of in-vitro diagnostic test kits for the detection of early stage colorectal cancer.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2011-04-11

Latest Revision Date: 2024-09-12

Effective Date: 2024-10-03

Expiry Date: 2027-10-02

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...making excellence a habit.™

Certificate No: FM 572228

Location

LGC Clinical Diagnostics, Inc.
25 Birch Street
Milford
Massachusetts
01757
USA

Registered Activities

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.

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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

Information and Contact:

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