

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LGC Clinical Diagnostics, Inc.

910 Clopper Road
Gaithersburg
Maryland
20878
USA

Holds Certificate Number:

FM 735301

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 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-08-17

Latest Revision Date: 2023-08-08

Effective Date: 2023-10-03

Expiry Date: 2026-10-02

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