

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Genedrive Diagnostics Ltd
48 Grafton Street
Manchester
Greater Manchester
M13 9XX
United Kingdom

Holds Certificate Number:

MD 801236

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

The design, development and manufacture of nucleic acid based molecular IVD assays and thermal cycler instruments for professional use in a near patient or laboratory setting.

Transferred from: UL LLC® (UL Solutions)
Certificate number: 1854.231009

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-04-16

Latest Revision Date: 2024-04-16

Effective Date: 2024-04-16

Expiry Date: 2026-10-08



Page: 1 of 1

...making excellence a habit.™