

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Prestige Diagnostics UK Ltd
65 Fenaghy Road
Galgorm
County Antrim
BT42 1HW
United Kingdom

Holds Certificate Number:

MD 769967

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

Manufacture and Distribution of In Vitro Diagnostic calibrators, controls and assays including ELISA and Rapid tests in the areas of Clinical Chemistry, Latex Serology, Blood Grouping, Immunochemistry, Haemostasis and Infectious diseases. Distribution of Molecular biology Assays and In Vitro Diagnostic Analysers.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-10-05

Latest Revision Date: 2024-03-01

Effective Date: 2024-04-10

Expiry Date: 2027-04-09

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