

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abingdon Health PLC
York Biotech Campus
Sand Hutton
York
YO41 1LZ
United Kingdom

Holds Certificate Number:

MD 725267

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

The design, development and manufacture of lateral flow devices and ELISA kits, reagents and device readers for in-vitro diagnostic medical use, including for use in the diagnosis and management of infectious diseases and immune status.

Previous certificate expired: 2021-12-09
Recertification audit ended: 2021-12-09

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-07-22

Latest Revision Date: 2023-10-19

Effective Date: 2021-12-16

Expiry Date: 2024-12-09



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