

Certificate of Registration

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

This is to certify that:

QuantuMDx Group Ltd
Lugano Building
57 Melbourne Street
Newcastle upon Tyne
NE1 2JQ
United Kingdom

Holds Certificate Number:

MD 676256

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

Design, development, manufacture and service of molecular diagnostic IVD assays and systems, including instrumentation and software, for the diagnosis of communicable disease.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-03-19

Latest Revision Date: 2024-01-31

Effective Date: 2024-03-19

Expiry Date: 2027-03-18



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