



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

Page: 1 of 1

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.