

Certificate of Registration

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

This is to certify that:

Yourgene Health UK Ltd
Skelton House
Lloyd Street North
Manchester Science Park
Manchester
M15 6SH
United Kingdom

Holds Certificate Number:

MD 716374

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 distribution of in-vitro diagnostic reagents and associated software for assessment of genetic abnormalities and infectious diseases. Installation and servicing of software used for genetic analysis. Provision of contract design, development, manufacture and distribution of in-vitro diagnostic reagents and associated software for assessment of genetic abnormalities and infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-13

Latest Revision Date: 2024-01-17

Effective Date: 2024-01-26

Expiry Date: 2027-01-25

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