

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - 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

Facility ID Number: F005334

Holds Certificate No:

MDSAP 726135

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-01-26

Effective Date: 2023-04-13

Expiry Date: 2024-01-25



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

...making excellence a habit.™

Certificate No: **MDSAP 726135**

Location

Registered Activities

Yourgene Health UK Ltd
Citylabs 1.0
Nelson Street
Manchester
M13 9NQ
United Kingdom
Facility ID Number: F005334

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.

Yourgene Health UK Ltd
Skelton House
Lloyd Street North
Manchester Science Park
Manchester
M15 6SH
United Kingdom
Facility ID Number: F005334

Design, Development and Manufacture of in-vitro diagnostic reagents and associated software for assessment of genetic abnormalities and infectious diseases.



Original Registration Date: 2021-01-26

Effective Date: 2023-04-13

Expiry Date: 2024-01-25

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.