

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Youngene Health UK Ltd**
Citylabs 1.0
Nelson Street
Manchester
M13 9NQ
United Kingdom

Facility ID Number: F005334

Holds Certificate No: **MDSAP 726135**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-01-26

Effective Date: 2021-09-23

Expiry Date: 2024-01-25



BSI Group America Inc. is an MDSAP authorized auditing organization

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 Rutherford House Manchester Science Park Manchester M15 6SZ 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 Greenheys Business Centre Pencroft Way Manchester Science Park Manchester M15 6JJ United Kingdom Facility ID Number: F005334	Assembly, labelling, storage and distribution.

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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.