

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

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: 2024-01-26

Expiry Date: 2027-01-25



BSI Group America Inc. is an MDSAP recognised auditing organization