EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 754552 R000

Manufacturer: Yourgene Health UK Ltd

Address:
Skelton House
Lloyd Street North
Manchester Science Park
Manchester
M15 6SH
United Kingdom

Single Registration Number: GB-MF-000024810

EU Authorised Representative: Advena Ltd.

Address:
Tower Business Centre
2nd Flr.
Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-11-01**

Current Issue Date: **2023-11-01**

Starting Validity Date: **2023-11-01**

Expiry Date: **2028-10-31**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0106 Genetic Testing IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	In vitro diagnostic molecular biology devices for qualitative detection of gene mutations intended for screening of cancer patients subject to 5-fluorouracil based treatment regimes

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3494191	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.