By Royal Charter

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 Global Regulatory & Quality

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

Current Issue Date: **2024-10-03**

Starting Validity Date: **2024-10-03**

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

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W010603 Multiple Parameters - 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
W010601 Inborn Gene or Chromosome Alterations 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 Cystic Fibrosis Transmembrane Conductance Regulator gene mutations intended for patient screening.

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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
2023-11-01	3494191	Issued
Current	30250678	Supplemented – Addition of Class C Generic Device Group: W010601 IVP 3011 Amended – Update to EMDN code from W0106 to W010603

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