

# 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.

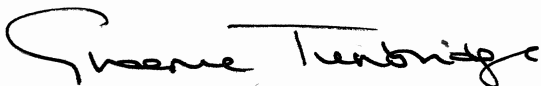
**Address:**

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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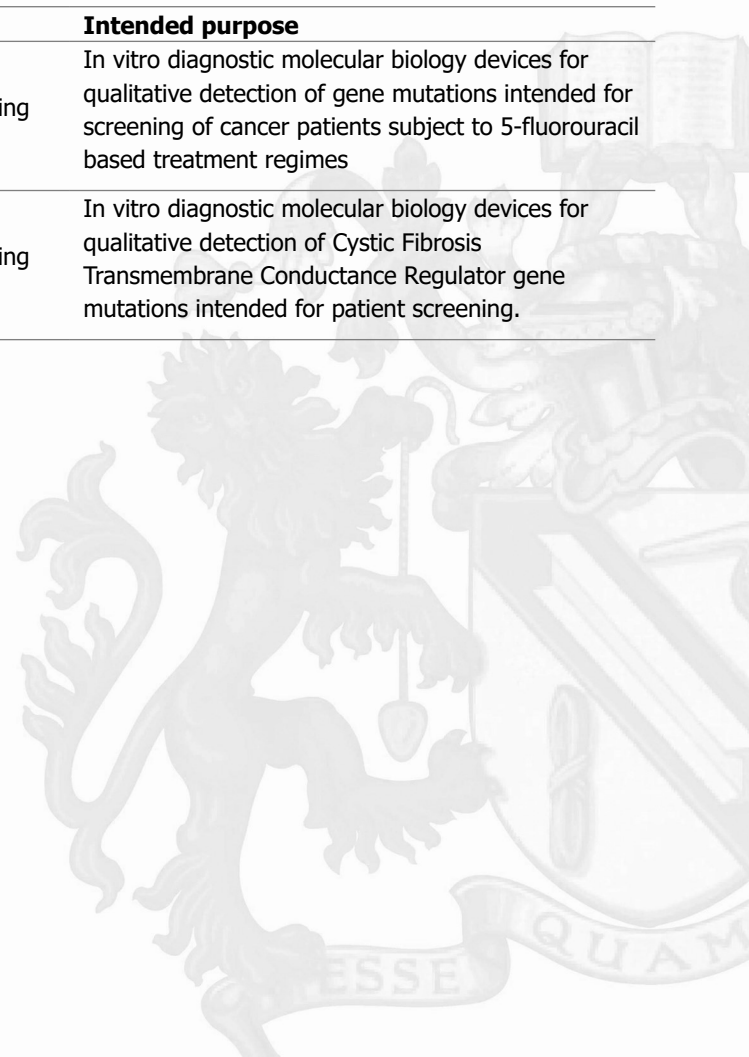
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## Device Schedule: Class D, C and B devices

| Class C devices                                                                                                                                                        | Intended purpose                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| W010603 Multiple Parameters - Genetic Testing                                                                                                                          | 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 |
| IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS) |                                                                                                                                                                                       |
| W010601 Inborn Gene or Chromosome Alterations                                                                                                                          | In vitro diagnostic molecular biology devices for qualitative detection of Cystic Fibrosis Transmembrane Conductance Regulator gene mutations intended for patient screening.         |
| IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS) |                                                                                                                                                                                       |



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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](mailto: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<br>Amended – Update to EMDN code from W0106 to W010603 |



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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.

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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.