EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 716372**

Issued To: **Yourgene Health UK Ltd**
Citylabs 1.0
Nelson Street
Manchester
M13 9NQ
United Kingdom

In respect of:

The design and manufacture of nucleic acid reagents and software for evaluation of the risk of trisomy 21

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2019-09-18** Date: **2022-03-17** Expiry Date: **2025-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 716372

Issued To:

Yourgene Health UK Ltd
Citylabs 1.0
Nelson Street
Manchester
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Product Code	Description	Intended purpose
Annex II List B		
IVD0308	IONA® test (including software) PMH-IONA-2015-001-192 IONA® test HT (including software) PMH-IONA-2016-002-192 IONA® test M (including software) PMH- 10141010 IONA® test AR (including software) PMH-10141020 IONA® test AS (including software) 10141030 IONA® Nx cfDNA Library Prep Dx Kit (96) (including software) 10141040	In vitro nucleic acid screening tests measuring the likelihood of Trisomy, including Trisomy 21, in the fetus.

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 716372**
Date: **2022-03-17**
Issued To: **Yourgene Health UK Ltd**
Citylabs 1.0
Nelson Street
Manchester
M13 9NQ
United Kingdom

Date	Reference Number	Action
18 September 2019	3061078	First Issue. Transfer from another Notified Body.
12 June 2020	3205824	Change of the company name from Premaitha Health to Yourgene Health UK Limited. Addition of IONA® Nx cfDNA Library Prep Dx Kit (96) (including software) to certificate. The addition of Delta Diagnostics (UK) Ltd trading as Elucigene Diagnostics as an additional subcontractor.
26 January 2021	3298082	Renewal with a change of Legal Manufacturer address, removal of Delta Diagnostics as a subcontractor & addition of Yourgene Health UK Limited, Rutherford House & Greenheys Business Centre as a subcontractor.
07 April 2021	3389667	Addition of subcontractor as EU Rep.
17 March 2022	3653301	Change of IVDD expiry date according to Regulation (EU) 2022/112

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3		
02 November 2022	3731914	Addition of new subcontractor: Yourgene Health UK Limited, Skelton House, Manchester Science Park, Manchester, M15 6SH United Kingdom
23 March 2023	3854592	Change of legal manufacturer address to: Skelton House, Lloyd Street North, Manchester Science Park, Manchester M15 6SH United Kingdom
07 March 2024	30109002	Scope restriction for products: IONA® test (including software) PMH-IONA-2015-001-192 IONA® test HT (including software) PMH-IONA-2016-002 IONA® test AS (including software) 10141030

Inspiring trust for a more resilient world.

07 March 2024

Yourgene Health UK Ltd
Skelton House
Lloyd Street North
Manchester Science Park
Manchester
M15 6SH
United Kingdom

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 716372	98/79/EC Annex IV excluding Sections 4 and 6	30109002	Scope restriction for products: IONA® test (including software) PMH-IONA-2015-001-192 IONA® test HT (including software) PMH-IONA-2016-002 IONA® test AS (including software) 10141030

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices