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By Royal Charter

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

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
M13 9NQ
United Kingdom

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.

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

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This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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

Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre 2nd Flr, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Sagentia Ltd Harston Mill Harston Cambridge CB22 7GG United Kingdom	**Software**
Yourgene Health UK Limited Rutherford House Pencroft Way Manchester Manchester Science Park M15 6SZ UK	**Assembly** **Design** **Labelling**

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

Subcontractor:	**Service(s) supplied**
Yourgene Health UK Ltd Greenheys Business Centre Pencroft Way Manchester Science Park Manchester M15 6JJ United Kingdom	**Assembly** **Labelling**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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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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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
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Yourgene Health

Including Premaitha Health and Eucigene Diagnostics

Declaration of Conformity

Yourgene Health UK Limited, trading as Yourgene Health, hereby declares that the *in vitro* diagnostic medical device(s) listed below comply with the provisions of the EU Directive 98/79/EC on *in vitro* diagnostic medical devices and The Netherlands Decree of 22 June 2001 (Decree on in-vitro diagnostics), reference: Official Gazette No. 385 of 2001 / Besluit van 22 juni 2001 (Besluit in-vitro diagnostica), referentie: Staatsblad nr 385 van 2001:

Placed on the market by and issued under the sole responsibility of:

Yourgene Health UK Limited
Citylabs 1.0
Nelson Street
Manchester
M13 9NQ
UK

Product Name	Product Code	Description
IONA® test (including software)	PMH-IONA-2015-001-192	192 Test
IONA® *HT* test (including software)	PMH-IONA-2016-002-192	192 Test
IONA® *M* test (including software)	10141010	192 Test
IONA® *AR* test (including software)	10141020	192 Test
IONA® *AS* test (including software)	10141030	192 Test

Classification: Annex II, List B
EDMS: 16.01.03 Chromosomal Disorders
GMDN: 59947 Multiple congenital aneuploidy screening IVD, kit, nucleic acid technique

Conformity Route: Annex IV, excluding Sections 4 and 6, conforming to the Essential Requirements as stipulated in Annex I of the EU Directive 98/79/EC on *in vitro* diagnostic medical devices

Intended Use Statement: The IONA test is an automated in vitro nucleic acid screening test for use in a higher risk population that measures the likelihood that a pregnant woman is carrying a foetus with Trisomy 13 or 18 or 21. The test is intended to be used by a clinician in combination with other risk factors to estimate the risk of an affected pregnancy. The IONA test is not intended to be used as a diagnostic test to confirm the presence of foetal Chromosome 13, 18 or 21 Trisomy.

Intended User: Professional

Notified Body: BSI Group The Netherlands B.V. Notified Body Identification Number: 2797

EU Authorised Representative: Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

EC Certificate No.: CE 716372 (Expiry Date: 26 May 2024)

Quality System Certified to: ISO 13485:2016 & EN ISO 13486:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

QMS Certificate No.: MD 716374 (Expiry Date: 25 January 2024)

Yourgene Health

Including Premaitha Health and Elucigene Diagnostics

Harmonised Standards:	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
	BS EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
	BS EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
	BS EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use
	BS EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
	BS EN ISO 17511:2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
	BS EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
	BS EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes

Natalie Wide
Director of QA/RA

20 Oct 2021
Date of Issue