



# EC CERTIFICATE

## Premaitha Limited

Rutherford House  
Manchester Science Park  
Manchester M15 6SZ  
United Kingdom

## EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:

**The design, development and manufacture of in vitro diagnostic reagents and associated software for non-invasive assessment of genetic abnormalities including Trisomy 21.**

Device Classification:

**Annex II, list B**

Device Descriptions:

**IONA® Test (including software)  
IONA® Test HT (including software)  
IONA® Test M (including software)  
IONA® Test AR (including software)  
IONA® Test AS (including software)**

Model:

**As Described in Attachment 1**

File Number	A28233	Cycle Start Date	03 February 2015
Certificate No.	732.170822	Effective Date	22 August 2017
		Expiry Date	28 January 2018

Authorised by

**C.H. Tonkin**  
**Certification Manager**

For and on Behalf of UL International (UK) Ltd

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11616337, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required.**

## Notified Body

# 0843



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### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
IONA® Test (including software)	PMH-IONA-2015-001-192	Annex II List B
IONA® Test HT (including software)	PMH-IONA-2016-002-192	Annex II List B
IONA® Test M (including software)	10141010	Annex II List B
IONA® Test AR (including software)	10141020	Annex II List B
IONA® Test AS (including software)	10141030	Annex II List B

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