



EC CERTIFICATE

Premaitha Health

Rutherford House
Manchester Science Park
Manchester M15 6SZ
United Kingdom

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, section 3 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)

Model:

PMH-IONA-2015-001-192

PMH-IONA-2016-002-192

File Number	A28233	Cycle Start Date	03 February 2015
Certificate No.	732.161115	Effective Date	15 November 2016
		Expiry Date	25 January 2018

Authorised by

Brian C. Rodgers
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 SR 3314434.927142, 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

IVDD A4 S3 FQ

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom