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.

Device Classification:
Annex II, list B

Device Descriptions:
IONA® Test (including software)

Model:
PMH-IONA-2015-001-192

File Number	A28233	Cycle Start Date	03 February 2015
Certificate No.	732.150203	Effective Date	03 February 2015
		Expiry Date	25 January 2018

Authorised by

Ivor Barrett
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 4786637192, 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

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