Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Premaitha Limited
Rutherford House
Manchester Science Park
Manchester, M15 6SZ
United Kingdom

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 00001727/C
Original Approval:	26 January 2018
Current Certificate:	26 January 2018
Certificate Expiry:	25 January 2021

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ, United Kingdom.

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 00001727/C SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Premaitha Limited
Rutherford House
Manchester Science Park
Manchester, M15 6SZ
United Kingdom

Annex II List B Products

IONA® Test (including software) PMH-IONA-2015-001-192
IONA® Test HT (including software) PMH-IONA-2016-002-192
IONA® Test M (including software) 10141010
IONA® Test AR (including software) 10141020
IONA® Test AS (including software) 10141030

Schedule Issue: 01

Date of Schedule Issue: 26 January 2018

LRQA Notified Body Number 0088

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