



## 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.

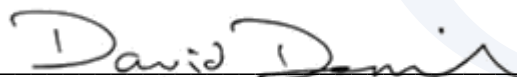
Certificate No: LRQ 00001727/C

Original Approval: 26 January 2018

Current Certificate: 26 January 2018

Certificate Expiry: 25 January 2021

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



**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



Issued by: Lloyd's Register Quality Assurance Limited