



EC CERTIFICATE

IDx, LLC

485 Highway 1 West
Iowa City, IA 52246 UNITED STATES

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of medical device software for detection of disease in retinal images

Device Classifications:

Class IIa

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on 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 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number A18142
Certificate Number 694.160423
Initial Issue Date April 23, 2013

Cycle Start Date April 23, 2016
Effective Date April 23, 2016
Expiry Date April 22, 2019

Authorised by

Paul Daysh

Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



Check Certificate
Status: [here](#)

Notified Body
0843



EC CERTIFICATE

IDx, LLC

485 Highway 1 West
Iowa City, IA 52246 UNITED STATES

Attachment 1 of 1

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Diagnostic software	IDx-DR	IDx-DR	Class IIa	

File Number A18142
Certificate Number 694.160423
Initial Issue Date April 23, 2013

Cycle Start Date April 23, 2016
Effective Date April 23, 2016
Expiry Date April 22, 2019

Authorised by

Paul Daysh

Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



Check Certificate
Status: [here](#)

Notified Body
0843