

# CERTIFICATE

Number: 2110891CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Optical Imaging Ltd.**

5 Openheimer st.

Rehovot 76701

Israel

For the product category:

**Retinal imaging systems**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 2110891CN, initially dated 27 February 2008**  
**Addendum, initially dated 27 February 2008**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 December 2013  
Issued for the first time: 27 February 2008  
Revised: 15 June 2011  
Reissued: 1 December 2010

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

DEKRA Certification B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 26 356 2000 F +31 26 352 5800 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2110891CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Retinal imaging systems

Issued to:

**Optical Imaging Ltd.**  
5 Openheimer st.  
Rehovot 76701  
Israel

This certificate covers the following product(s):

- RFI system (Retinal Function Imager, Class IIa)

Initial date: 27 February 2008

Revision date: 15 June 2011

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.