

CERTIFICATE

Number: 2110891CE01



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Optical Imaging Ltd.5 Openheimer st.
76701 REHOVOT
ISRAEL

For the product category:

Retinal imaging systems

KEMA 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 February 27, 2008
Addendum, initially dated February 27, 2008

KEMA 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, section 3 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. 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: December 1, 2010
Issued for the first time: February 27, 2008drs. G.J. Zoetbrood
Managing Directordr. ir. G.W. Bos
Certification Manager

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KEMA MedicalKEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands
T +31 26 3 56 20 00 F +31 26 3 52 58 00 customer@kema.com www.kema.com Registered Arnhem 09085396

ADDENDUM

Belonging to certificate: 2110891CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Retinal imaging systems

Issued to:

Optical Imaging Ltd.

5 Openheimer st.
76701 REHOVOT
ISRAEL

This certificate covers the following product(s):

- RFI (Retinal Function Imager)

Initial date: February 27, 2008

Revision date: -



drs. G.J. Zoetbrood
Managing Director



dr. ir. G.W. Bos
Certification Manager

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