



Declaration of Conformity

**HEIDELBERG
ENGINEERING**

Heidelberg Engineering GmbH
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Product

SPECTRALIS[®] HRA
SPECTRALIS[®] HRA 100[®] Heidelberg Retina Angiograph
 - 400 nm and 780 nm light sources
 - 1000, 2000, 3000 and 4000 images

SPECTRALIS[®] HRT
SPECTRALIS[®] OCT Heidelberg Retina Tomograph
 - 780 nm light source
 - 1000, 2000, 3000 and 4000 images
 - 1000, 2000, 3000 and 4000 images
 - 1000, 2000, 3000 and 4000 images
 - 1000, 2000, 3000 and 4000 images

SPECTRALIS[®] HRA + OCT
 - 400 nm and 780 nm light sources
 - 1000, 2000, 3000 and 4000 images

Classification (MDD Annex IX) IIIa

We hereby declare under our sole responsibility that the above-named product meets the provisions of the following EC Council Directive. All supporting documentation is attached under the umbrella of the manufacturer and authorised agent.

DIRECTIVE

Medical Device Directive: COUNCIL DIRECTIVE 90/269/EEC of June 1992 concerning medical devices

Notified Body: MEDDEV GmbH
 File no. 012
 D-70569 Heilbronn
 Germany

Notified Body Reference: **CE 012**

CE Certificate No.: 2012/012/012

Product Reference: AIMA (MDD 90/269/EEC)

Classification (MDD Annex II) Annex II

This declaration is valid for all devices within the scope, which are CE-marked after the signature of the issuer, until 31 September 2015.

Issue Date: Heilbronn, 25 June 2012

Signature: Dr. Gerhard Fries
 Position: Managing Director