

EC Certificate

Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 1230912-1

Manufacturer: CANON INC.
9-1, Imaikami-cho, Nakahara-ku
Kawasaki, Kanagawa, Kanagawa-ken
211-8501 Japan

Products:

- Digital Radiography Devices
- Optical Coherence Tomography Systems
- Tonometers/Pachymeters
- Ophthalmic Software for Optical Coherence Tomography Systems and Retinal Cameras

Aspects of manufacture concerned with the conformity of the products with the metrological requirements of:

- Auto Ref-Keratometers

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 12031297 013

Effective date: 2020-10-08

Expiry date: 2024-05-26

Issue date: 2020-10-08



Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	CANON INC. 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa, Kanagawa-ken 211-8501 Japan	Digital Radiography Devices, Optical Coherence Tomography Systems, Tonometers/Pachymeters, Ophthalmic Software for Optical Coherence Tomography Systems and Retinal Cameras Aspects of manufacture concerned with the conformity of the products with the metrological requirements of: Auto Ref-Keratometers
/02	CANON COMPONENTS. INC. 3461-1, Oaza-Shichihongi, Kamisato-machi, Kodama-gun Saitama 369-0393 Japan	Digital Radiography Devices, Optical Coherence Tomography Systems, Tonometers/Pachymeters, Ophthalmic Software for Optical Coherence Tomography Systems and Retinal Cameras, Auto Ref- Keratometers

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