EC DESIGN-EXAMINATION CERTIFICATE

Number: 2188436DE02

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Implandata Ophthalmic Products GmbH

Kokenstrasse 5
30159 Hannover
Germany

For the product

eyemate®-IO/KP, intraocular pressure sensor for measurement of intraocular pressure in patient with Boston keratoprosthesis

Documents, that form the basis of this certificate:

Certification Notice 2188436CN, initially dated 8 November 2016
CE Marking of Conformity 2188436CE01
Addendum, initially dated 19 April 2019

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 2 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 2 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 19 April 2019
Reissued: 1 June 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2188436DE02

EC DESIGN-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

eyemate®-IO/KP, intraocular pressure sensor for measurement of intraocular pressure in patient with Boston keratoprosthesis

Issued to:

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
30159 Hannover
Germany

This certificate covers the following product(s):

- eyemate®-/IO/KP Implant
  - o 11.3 mm (IMP130001)
  - o 11.7 mm (IMP130002)
  - o 12.1 mm (IMP130003)
- eyemate®-IO Reader device
  - o Mesograph (REA100013)
- eyemate®-IO/KP surgical set (SET130001-DEU)

Initial date: 19 April 2019
Revision date: 1 June 2019

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