EC CERTIFICATE

Number: 2188436CE01

Full Quality Assurance System

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

Manufacturer:

Implandata Ophthalmic Products GmbH

Kokenstrasse 5
30159 Hannover
Germany

For the product category(ies)

Intraocular pressure sensor for measurement of intraocular pressure in patients with primary open angle glaucoma and Boston keratoprosthesis

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 2188436CN, initially dated 8 November 2016
Addendum, initially dated 24 May 2017

DEKRA hereby declares that the above mentioned manufacturer 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. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex 2 of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance. For placing on the market of Active implantable medical devices an additional EC design examination certificate according to Annex 2 (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities 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: 26 May 2024
Issued for the first time: 24 May 2017
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: 2188436CE01

CE MARKING OF CONFORMITY
ACTIVE IMPLANTABLE MEDICAL DEVICES

Intraocular pressure sensor for measurement of intraocular pressure in patients with primary open angle glaucoma and Boston keratoprosthesis

Issued to:

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
30159 Hannover
Germany

This certificate covers the following product(s):

- eyemate®-IO, intraocular pressure sensor for measurement of intraocular pressure in patients with primary open angle glaucoma

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

Initial date: 24 May 2017
Revision date: 1 June 2019

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B.T.M. Holtus
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