

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 2188436DE01

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

Manufacturer:

**Impladata Ophthalmic Products GmbH**  
Kokenstrasse 5  
30159 Hannover  
Germany

For the product

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

Documents, that form the basis of this certificate:

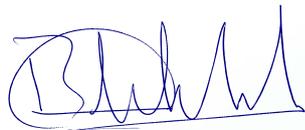
**Certification Notice 2188436CN, initially dated 8 November 2016**  
**CE Marking of Conformity 2188436CE01**  
**Addendum, initially dated 24 May 2017**

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: 1 June 2020  
Issued for the first time: 24 May 2017

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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

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# ADDENDUM

Belonging to certificate: 2188436DE01

1/1

## EC DESIGN-EXAMINATION ACTIVE IMPLANTABLE MEDICAL DEVICES

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

Issued to:

**Impladata Ophthalmic Products GmbH**  
**Kokenstrasse 5**  
**30159 Hannover**  
**Germany**

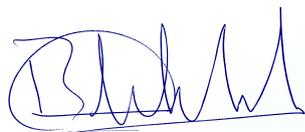
This certificate covers the following product(s):

- EYEMATE-IO Implant
  - o 11.3 mm (IMP010001)
  - o 11.7 mm (IMP010002)
  - o 12.1 mm (IMP010003)
- EYEMATE-IO Reader device
  - o Mesograph (REA100000)
- Medical Accuject Injector EM-IO 1.1 (SUG010200)
- EYEMATE-IO surgical set (SET010001-DEU)

Initial date: 24 May 2017

Revision date: 13 March 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt  
Certification Manager

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