Number: 2246552TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Implandata Ophthalmic Products GmbH

Kokenstraße 5
30159 Hannover
Germany
SRN ID.: DE-MF-000005431

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 EU- Regulation which apply to them:

0344

Supplement to certificate: 2188436CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Principal Certification Manager

First Issued: **17 June 2021** Date: **24 June 2021** Expiry date**: 1 June 2026**

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra-product-safety.com Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Class III	
Basic UDI-DI: 426064817IMP107A eyemate®-IO implant, 11.3mm, 11.7mm , 12.1mm (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure
Basic UDI-DI: 426064817IMP137G eyemate®-IO/KP, 11.3mm, 11.7mm , 12.1mm (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure
Basic UDI-DI: 426064817IMP217F eyemate®-SC implant (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure
Basic UDI-DI: 426064817REA326L eyemate®-Reader Set, eyemate®-Key, eyemate®-Cable Antenna (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure

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Basic UDI-DI: 426064817INJ4576 Medicel ACCUJET Injector EM-IO 1.1 (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure
Basic UDI-DI: 426064817PAD215C Silicone paddings (Z121201, ophthalmology instruments for evaluation and diagnosis)	*Intended Purpose:* Intraocular pressure sensor for measurement of intraocular pressure

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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Date of Issue certificate	Certification Notice Reference	Action
17 June 2021	2188436CN08	First issue
24 June 2021	2188436CN08.1	Revised

First Issued: **17 June 2021** Date: **24 June 2021** Expiry date**: 1 June 2026**

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