Number: 4202074CE01

EU Quality Management System Certificate

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

Manufacturer:

NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi 443-0038
Japan
SRN ID.: TBD

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: 4201915CN

Authorized Representative: NIDEK S.A. Ecopark, rue Benjamin Franklin, 94370 Sucy En Brie, France

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.M. McKenzie
Principal Certification Manager

First Issued: 29 November 2021 Date: 21 September 2023 Expiry date: 1 November 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.nl Company registration 09085396

Number: 4202074CE01

EU Quality Management System Certificate

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

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

Other active non-implantable devices for monitoring and/or diagnosis (MDA0204, class Im)
Device Name: PD METER PM-700

Active non–implantable devices utilising non-ionizing radiation (MDA 0202, class IIa)
- Non-Mydriatic Auto Fundus Camera AFC-330 - OPTICAL BIOMETER AL-Scan - SPECULAR MICROSCOPE CEM-530 - GONIOSCOPE GS-1 - LASER SPECKLE FLOWGRAPHY LSFG-RetFlow - Scanning Laser Ophthalmoscope Mirante - Microperimeter MP-3 - Optical Coherence Tomography RS-3000 Advance - Optical Coherence Tomography RS-330 - ECHOSCAN US-4000 - ECHOSCAN US-500 - Optical Coherence Tomography RS-1

Other active non-implantable devices for monitoring and/or diagnosis (MDA0204, class IIa)
- REFRACTIVE POWER / CORNEAL ANALYZER OPD-Scan III - AUTO REFRACTOMETER AR-1 / AR-1a / AR-1s - AUTO REFRACTOMETER AR-F - AUTO REF/KERATOMETER ARK-1/ARK-1a/ARK-1s/ARK-1e - AUTO REF/KERATOMETER ARK-F - HANDHELD REF/KERATOMETER HandyRef-K - HANDHELD REFRACTOMETER HandyRef - NON CONTACT TONOMETER NT-510 - NON CONTACT TONOMETER NT-530 - NON CONTACT TONO/PACHYMETER NT-530P - AUTO REF/KERATO/TONO/PACHYMETER TONOREF III - NON CONTACT TONO/PACHYMETER NT-1p - NON CONTACT TONOMETER NT-1/NT-1e

First Issued: 29 November 2021 Date: 21 September 2023 Expiry date: 1 November 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.nl Company registration 09085396

Number: 4202074CE01

EU Quality Management System Certificate

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

Conditions for or limitations to the validity of this certificate:

- For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements

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.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	29 November 2021	4201915CN04	First issue
1	8 December 2021	4201915CN05	Revised
2	19 July 2022	4201915CN09	Revised
3	27 July 2022	4201915CN09.1	Revised
4	7 July 2023	4201915CN14	Revised
5	21 August 2023	4201915CN15	Revised
6	21 September 2023	4201915CN15.1	Revised

First Issued: 29 November 2021 Date: 21 September 2023 Expiry date: 1 November 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.nl Company registration 09085396