Number: 4202074CE02

# 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.A. McKenzie
Principal Certification Manager

First Issued: 7 March 2023 Date: 7 June 2023 Expiry date: 7 March 2028



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



2184-5

Number: 4202074CE02

# 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):

| Therapeutic and Surgical Ophtholmological Treatments Instruments (Z121202, class IIb) | |
|---|---|
| **Device Name:**<br>**OPHTHALMIC YAG LASER SYSTEM YC-200** | Intended Purpose:<br><br>The ophthalmic YAG laser system YC-200 is indicated for the performance of posterior capsulotomy, posterior membranectomy, pupillary membranectomy, iridotomy (hole in the iris) and selective laser trabeculoplasty. |
| **Device Name:**<br>**GREEN LASER PHOTOCOAGULATOR GYC-500** | Intended Purpose:<br><br>Intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty. |
| **Device Name:**<br>**Multicolor Laser Photocoagulator MC-500** | Intended Purpose:<br><br>intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty |
| **Device Name:**<br>**YELLOW LASER PHOTOCOAGULATOR YLC-500** | Intended Purpose:<br><br>Intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty. |

First Issued: 7 March 2023 Date: 7 June 2023 Expiry date: 7 March 2028



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



2184-5

Number: 4202074CE02

# 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:

- N/A

## 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 | 7 March 2023 | 4201915CN11 | First issue |
| 1 | 27 March 2023 | 4201915CN12 | Revised |
| 2 | 7 June 2023 | 4201915CN13.1 | Correction |

First Issued: 7 March 2023 Date: 7 June 2023 Expiry date: 7 March 2028



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



2184-5