

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:

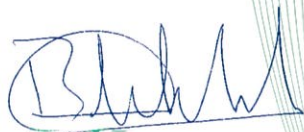
0344

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

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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

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

Therapeutic and Surgical Ophthalmological Treatments Instruments (Z121202, class IIb)

Device Name:
OPHTHALMIC YAG LASER SYSTEM YC-200

Intended Purpose:

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:
GREEN LASER PHOTOCOAGULATOR GYC-500

Intended Purpose:

Intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

Device Name:
Multicolor Laser Photocoagulator MC-500

Intended Purpose:

intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty

Device Name:
YELLOW LASER PHOTOCOAGULATOR YLC-500

Intended Purpose:

Intended to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

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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

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