

CERTIFICATE

Number: 4202064

The management system of the organization(s) and locations mentioned on the addendum belonging to:

NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi 443-0038
Japan

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

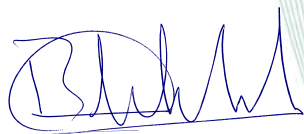
Scope:

Design and Development, Production and Distribution of Ophthalmic Surgical Lasers, Ophthalmic Diagnostic Active Devices, Ophthalmic Surgical Devices, Optometric Equipment, Ophthalmic Data processing Software, Intraocular lenses, Intraocular lenses Preloaded into Inserters

Certificate expiry date: 16 January 2025
Certificate effective date: 16 January 2022
Certified since: 21 August 2019

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 4202064

The management system of the organization(s) and/or location(s) of:

NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi 443-0038
Japan

Certified organization(s) and/or locations:

Different scope

NIDEK CO., LTD., Hiroishi Plant
34-14 Maehama, Hiroishi-cho,
Gamagori
Aichi 443-0038

Design and Development, Servicing and Distribution of
Ophthalmic Surgical Lasers, Ophthalmic Diagnostic Active
Devices, Ophthalmic Surgical Devices, Optometric Equipment,
Ophthalmic Data processing Software

NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori
Aichi 443-0036

Manufacturing and Distribution of Ophthalmic Surgical Lasers,
Ophthalmic Diagnostic Active Devices, Ophthalmic Surgical
Devices, Optometric Equipment, Ophthalmic Data processing
Software

NIDEK CO., LTD Hiroishi Plant 7th
Building
32 Higashihama, Hiroishi-cho,
Gamagori
Aichi 443-0038

Design and Development and Manufacturing and Distribution of
Intraocular Lenses, Intraocular Lenses Preloaded into Inserters

Addendum expiry date: 16 January 2025
Addendum effective date: 16 January 2022