

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:

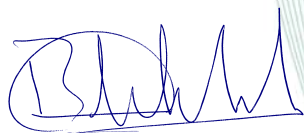
Design and Development, manufacture, servicing, packaging, and Distribution of Ophthalmic Surgical Lasers, Ophthalmic Diagnostic Active Devices, Ophthalmic Surgical Devices, Optometric Equipment, Ophthalmic Data processing Software, Intraocular lenses, Intraocular lenses Preloaded into Inserters

Ethylene Oxide Sterilization of Intraocular Lenses, Intraocular Lenses Preloaded into Inserters, and Ophthalmic Surgical Device in accordance with EN ISO 11135:2014

Certificate expiry date: 16 January 2028
Certificate effective date: 16 January 2025
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.M. McKenzie
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
Japan

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
Japan

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
Japan

Design and Development and Manufacturing and Distribution of
Intraocular Lenses, Intraocular Lenses Preloaded into Inserters,
and Ophthalmic Surgical Devices
The provision of Ethylene Oxide Sterilization services fulfilling
applicable quality management system requirements within EN
ISO 11135:2014 and ISO 11135:2014

NIDEK CO., LTD. Product Center
67-21 Hama-cho
Gamagori-Shi 443-0036
Japan

(Re-) Packaging and Distribution of Ophthalmic Surgical Lasers,
Ophthalmic Diagnostic Active Devices, Ophthalmic Surgical
Devices, Optometric Equipment, Ophthalmic Data processing
Software

Addendum expiry date: 16 January 2028
Addendum effective date: 16 January 2025