ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 023653 0197 Rev. 00

Holder of Certificate: **NIDEK CO., LTD.**
34-14 Maehama, Hiroishi-cho, Gamagori
Aichi
443-0038 JAPAN

Facility(ies):
NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aichi, 443-0036 JAPAN

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:
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

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JAQ235034768

Valid from: 2019-01-17
Valid until: 2022-01-16

Date, 2019-01-17

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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