Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 23653 195

Manufacturer:	**NIDEK CO., LTD.** 34-14 Maehama, Hiroishi-cho, Gamagori Aichi 443-0038 JAPAN
EC-Representative:	**NIDEK S.A.** Europarc, 13 rue Auguste Perret 94042 Créteil FRANCE
Product Category(ies):	**Ophthalmic Surgical Lasers,** **Ophthalmic Diagnostic Active Devices,** **Ophthalmic Surgical Devices,** **Ophthalmic Data Processing Software,** **Intraocular Lenses,** **Intraocular Lenses Preloaded into Inserters**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD

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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
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Facility(ies):

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

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