Eye & Health Care
NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038 Japan
TEL +81-533-67-8895 FAX +81-533-68-1320
URL http://www.nidek.com
e-mail info@nidek.co.jp

Document No.: BRQFQ16GYC-5QQEUQ1

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co. Ltd.
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
European Representative	NIDEK s.a. Europarc, 13 rue Auguste Ferret, 94042 Creteil, France
Identification of device	GREEN LASER PHOTOCOAGULATOR
Model No.	GYC-500
Classification (Annex IX, MDD)	lib
Category (Annex I, RoHS)	8

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer. The supporting technical documentation is also retained at NIDEK s.a., Europarc, 13 rue Auguste Perret, 94042 Creteil, France.

DIRECTIVES and STANDARDS

General applicable directives	Standards	Date CE Mark was affixed
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.	EN ISO13485, EN ISO14971, ISO15223-1, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-1-6, IEC60601-2-22, IEC60825-1, IEC62304, IEC62366, JIS Z0150, EN ISO10993-1, EN980	April 14, 2015 CE 0123
COUNCIL DIRECTIVE 2011/65/EU of 8 June 2011 concerning restriction of the use of certain hazardous substances in electrical and electronic equipment.	EN50581	April 14, 2015 CE

Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Miinchen, Germany

Certificate : Gl 13 07 23653 126 (Annex E, Section 3 of MDD)

Place: Aichi, Japan

Effective date: April 14, 2015

Signed by

M. Mihori

Masatoshi Mihori
General Marketing Manager
Quality Control Division
NIDEK Co., Ltd.

Date of signature: April 10. 2015

Digitally signed by Bas Luttikhuis
Date: 2024.11.13 17:05:40 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ