Form : QMS-S041-W36-F3 (Rev.1.4)

Eye & Health Care
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Document No. DOCGYC-500EU08

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co., Ltd.	SRN	N/A
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan		
European Representative name	NIDEK S.A.	SRN	FR-AR-000000341
European Representative address	Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE		
Identification of device	GREEN LASER PHOTOCOAGULATOR		
Model No.	GYC-500		
Classification(Annex IX, MDD)	IIb (Rule 9)		
Category (for RoHS)	8		
Basic UDI-DI	4987669220G6		

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directive(s)/Regulation. All supporting documentation is retained under the premises of the manufacturer. The supporting technical documentation is also retained at NIDEK S.A., Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE.

General applicable directive(s)/regulation	Notified Body	Date CE Marking was affixed
COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.	DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands Certificate No. : 4201915CE01 (Annex II , Section 3 of MDD)	April 14, 2015 CE 0344
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	**N/A**	April 14, 2015 CE

Place: Aichi, Japan

Effective date : October 4, 2021

Signed by

H. Shimazaki

Hiroshi Shimazaki
Director
Top Management
NIDEK Co., Ltd.

Date of signature : September 27, 2021