





# DECLARATION OF CONFORMITY

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

Notified Body : TÜV SÜD Product Service GmbH,  
Ridlerstr. 65, 80339 München, Germany  
 Certificate : G1 13 07 23653 126 (Annex II , Section 3 of MDD)

Place: Aichi, Japan  
 Signed by

Effective date: April 14, 2015

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

Date of signature: April 10. 2015