



Eye & Health Care

NIDEK CO., LTD.

34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
 Manufacturers, Exporters & Importers of Ophthalmic Instruments, and
 Opto-Electronics Instruments
 TEL +81-533-67-6611 FAX +81-533-67-6610
 URL <http://www.nidek.co.jp> <http://www.nidek.com>



Document No.: BRQF016OPD-SCANIIIIEU10

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 REFRACTIVE POWER / CORNEAL ANALYZER
 Model No. OPD-Scan III
 Classification(Annex IX, MDD) IIa
 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, IEC60601-1, IEC60601-1-2, IEC60601-1-6, ISO10342, ISO10343, EN ISO14971, EN ISO15004-1, ISO15004-2, IEC62304, IEC62366, ISO15223-1, JIS Z0150	March 29, 2011 
COUNCIL DIRECTIVE 2011/65/EU of 8 June 2011 concerning restriction of the use of certain hazardous substances in electrical and electronic equipment.	EN50581	March 27, 2014 

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

Effective date: April 7, 2014

Signed by

M. Mihori

Date of signature:

April 2, 2014

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