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.: BRQF016HandyRef-KEU01

# 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.<br>Europarc, 13 rue Auguste Perret, 94042 Créteil, France |
| Identification of device | HANDHELD REF/KERATOMETER |
| Model No. | HandyRef-K |
| Classification(Annex Ⅸ, MDD) | IIa |
| Category (Annex I, RoHS) | 8 |
| Classification(2000/299/EC, R&TTE) | 1 |

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, EN980, JIS Z 0150, ISO10342, ISO10343, EN ISO15004-1, EN ISO15004-2, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC62304, IEC62366 | May 1, 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 | May 1, 2015 CE |
| COUNCIL DIRECTIVE 1999/5/EC of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity | IEC60601-1, IEC60601-1-2, EN60950-1, EN62311, EN62479, EN301 489-1, EN301 489-17, EN300 328 | May 1, 2015 CE |

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: May 1, 2015

Signed by

Kan Ohtsuki
Corporate Advisor
NIDEK Co., Ltd.

Date of signature: Apr. 28, 2015