






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 HANDHELD REFRACTOMETER
 Model No. HandyRef
 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, EN ISO15004-1, EN ISO15004-2, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC62304, IEC62366	May 1, 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	May 1, 2015 
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 

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



Date of signature: Apr. 28, 2015

Kan Ohtsuki
Corporate Advisor
NIDEK Co., Ltd.