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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 AUTO REFRACTOMETER
 Model No. AR-1/AR-1a/AR-1s
 Classification(Annex IX, MDD) IIa

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

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

Standards :


Applicable Standards to this product are :

ISO13485, ISO10342, ISO15223-1, EN ISO14971, EN ISO15004-1, EN ISO15004-2, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC62304, IEC62366, IEC/TR60878

Notified Body : TÜV SÜD Product Service GmbH,
 Ridlerstr. 65, 80339 München, Germany
 Certificate : G1 13 05 23653 121 (Annex II , Section 3 of MDD)
 Date CE Mark was affixed : April 30, 2013

Place: Aichi, Japan
 Signed by

Effective date : July 24, 2013


 Kan Ohtsuki
 Director and General Manager,
 R&D Division,
 NIDEK Co., Ltd.

Date of signature : July 18, 2013