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
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Document No.: BRQF016ARK-1EU03

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. Europarc, 13 rue Auguste Perret, 94042 Créteil, France
Identification of device	AUTO REF/KERATOMETER
Model No.	ARK-1/ARK-1a/ARK-1s
Classification(AnnexⅨ, 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.

CE
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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, ISO10343, 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
Effective date : July 24, 2013

Signed by

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

Date of signature : July 18, 2013