Eye & Health Care
NIDEK CO., LTD.

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Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments
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Document No.: BRQF016AL-ScanEU04

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	OPTICAL BIOMETER
Model No.	AL-Scan
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, ISO10343, ISO17664, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC60601-2-37, IEC62304, IEC62366, EN ISO10993-1, EN ISO14971, ISO15223-1, EN ISO15004-1, ISO15004-2, JIS T1205	May 11, 2012 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	March 27, 2014 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: April 7, 2014

Signed by

M. Mihori

Date of signature: April 2, 2014

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