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.:BRQF016RS-330EU01

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 Coherence Tomography
Model No.	RS-330
Classification(Annex Ⅸ, MDD)	Ⅱa
Category (for 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, STANDARDS and NOTIFIED BODY

General applicable directives	Standards	Notified Body	Date CE Mark was affixed
COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.	EN ISO13485, EN ISO14971, IEC60825-1, ISO10940, EN ISO 15004-1, ISO 15004-2, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC62304, IEC62366, ISO15223-1, JIS Z 0150, EN980	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany Certificate : G1 13 07 23653 126 (Annex Ⅱ, Section 3 of MDD)	December 16, 2014 CE 0123
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	EN50581		December 16, 2014 CE

Place: Aichi, Japan
Effective date : December 16, 2014

Signed by

Kan Ohtsuki
Corporate Advisor,
NIDEK Co., Ltd.

Date of signature : Dec. 16, 2014