Eye & Health Care
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Document No.: DOCRS-3000AdvanceEU06

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-3000 Advance
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.

General applicable directives	Date CE Mark was affixed
COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.	May 18, 2012 CE 0123
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	April 10, 2014 CE

Notified Body : TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany

Certificate : G1 16 11 23653 180 (Annex Ⅱ, Section 3 of MDD)

Place: Aichi, Japan

Effective date : April 3, 2017

Signed by

A. Hayashi

Date of signature : Mar. 31. 2017

Akihiro Hayashi
Director
Quality Assurance Division
NIDEK Co., Ltd.