Eye & Health Care
NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
TEL +81-533-67-8895 FAX +81-533-68-1320
URL http://www.nidek.com
e-mail info@nidek.co.jp

Document No.: DOCTS-310EU02

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	Tabletop Refraction System
Model No.	TS-310
Classification(Annex Ⅸ, MDD)	I
Category (Annex I, RoHS)	8
Classification(2014/53/EU, RE)	1

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 of concerning medical devices	July 10, 2017 CE
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances	July 10, 2017 CE
Directive 2014/53/EU of the European Parliament and of the council on the market of radio equipment	October 12, 2017 CE

Place: Aichi, Japan
Effective date: October 12, 2017

Signed by

H. Torii

Hiroyuki Torii
Director
Top Management
NIDEK Co., Ltd.

Date of signature: October 12, 2017