Eye & Health Care
NIDEK CO., LTD.

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Document No. DOCTS-310EU06

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co., Ltd.	SRN	Not issued yet
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan		
European Representative name	NIDEK S.A.	SRN	FR-AR-000000341
European Representative address	Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE		
Identification of device	Tabletop Refraction System		
Model No.	TS-310		
Classification (Annex VIII, MDR)	I (Rule 13)		
Category (for RoHS)	8		
Classification(2014/53/EU, RE)	1		
Basic UDI-DI	4987669104G3		

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directive(s)/Regulation. All supporting documentation is retained under the premises of the manufacturer. The supporting technical documentation is also retained at NIDEK S.A., Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE.

General applicable directive(s)/regulation	Date CE Marking was affixed
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices	February 19, 2020 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
Signed by

K. Tohyama

Katsuaki Tohyama
Person responsible for regulatory compliance
Senior Manager
NIDEK Co., Ltd.

Effective date : October 21, 2021

Date of signature : October 18, 2021