Form : QMS-S041-W36-F3 (Rev.1.4)

Eye & Health Care
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Document No. DOCHandyRef-KEU14

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	HANDHELD REF/KERATOMETER		
Model No.	HandyRef-K		
Classification (Annex VIII, MDR)	IIa (Rule 10)		
Category (for RoHS)	8		
Classification (2014/53/EU, RE)	1		
Basic UDI-DI	4987669202G4		

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	Notified Body	Date CE Marking was affixed
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices	DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands Certificate No. : 4202074CE01 (Annex IX, Section 2 of MDR)	May 1, 2015 CE 0344
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	N/A	May 1, 2015 CE
Directive 2014/53/EU of the European Parliament and of the council on the market of radio equipment.	N/A	February 16, 2017 CE

Place: Aichi, Japan
Signed by

H. Tohyama

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

Effective date : March 3, 2023

Date of signature : February 21, 2023