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

Eye & Health Care
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Document No. DOCUS-4000EU24

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	ECHOSCAN		
Model No.	US-4000		
Classification (Annex VIII, MDR)	IIa (Rule 10)		
Category (for RoHS)	8		
Basic UDI-DI	4987669206GC		

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 : 4202074CE01 (Annex IX, Section 2 of MDR)	July 17, 2007 CE 0344
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	N/A	March 27, 2014 CE

Place: Aichi, Japan

Effective date : February 17, 2023

Signed by

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

Date of signature : February 2, 2023