



# DECLARATION OF CONFORMITY

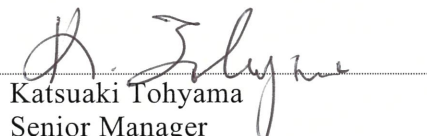
Manufacturer's name	NIDEK Co., Ltd.	SRN	Not issued yet
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan		
European Representative name	NIDEK S.A.	SRN	FR-AR-000000341
European Representative address	Ecoparc, rue Benjamin Franklin, 94370 Sucy En Brie, FRANCE		
Identification of device	REFRACTIVE POWER / CORNEAL ANALYZER		
Model No.	OPD-Scan III		
Classification (Annex VIII, MDR)	IIa (Rule 10)		
Category (for RoHS)	8		
Basic UDI-DI	4987669208GG		

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)	March 29, 2011  
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	N/A	March 27, 2014  

Place: Aichi, Japan  
 Signed by

Effective date : February 10, 2023

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

Date of signature : February 2, 2023