

# 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	NON CONTACT TONO/PACHYMETER		
Model No.	NT-1p		
Classification (Annex VIII, MDR)	IIa (Rule 10)		
Category (for RoHS)	8		
Classification (2014/53/EU, RE)	1		
Basic UDI-DI	4987669204G8		


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)	October 25, 2022  <b>CE</b> 0344
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	N/A	October 25, 2022  <b>CE</b>
COUNCIL DIRECTIVE 2014/53/EU of the European Parliament and of the council on the market of radio equipment	N/A	October 25, 2022  <b>CE</b>

Place: Aichi, Japan

Signed by

Effective date : October 25, 2022

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

Date of signature : October 20, 2022