Form : QMS-S041-W36-F2 (Rev. 1.4)

Eye & Health Care
NIDEK CO., LTD.

34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
TEL +81-533-67-8895 FAX +81-533-68-1320
URL www.nidek.com
e-mail info@nidek.co.jp

Document No. DOCSC-1600EU15

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co., Ltd. SRN N/A
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	SYSTEM CHART
Model No.	SC-1600
Classification (Annex VIII, MDR)	I (Rule 13)
Category (for RoHS)	8
Basic UDI-DI	4987669105G5

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 21, 2020 CE
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	April 2, 2014 CE

Place: Aichi, Japan

Effective date : September 30, 2021

Signed by

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

Date of signature : August 31, 2021