Eye & Health Care
NIDEK CO., LTD.

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Document No.DOCSL-2000EU05

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co. Ltd.
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
European Representative	NIDEK s.a. Europarc, 13 rue Auguste Perret, 94042 Créteil, France
Identification of device	SLIT LAMP
Model No.	SL-2000
Classification(Annex VIII, MDR)	I (Rule 13)
Category (for RoHS)	8
Basic UDI-DI	4987669101FV

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., Europarc, 13 rue Auguste Perret, 94042 Créteil, 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	March 9, 2020 CE
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	December 20, 2016 CE

Place: Aichi, Japan
Signed by

H. Shimazaki

Hiroshi Shimazaki
General Manager
Person responsible for regulatory compliance
NIDEK Co., Ltd.

Effective date : March 9, 2020

Date of signature : March 9, 2020

Digitally signed by Bas Dumitru
Date: 2024.11.13 17:35:03 EET
Reason: MoldSign Signature
Location: Moldova
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