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

Eye & Health Care
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Document No. DOCLM-7PEU09

# 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 | AUTO LENSMETER | | |
| Model No. | LM-7 / LM-7P | | |
| Classification (Annex VIII, MDR) | I (Rule 13) | | |
| Category (for RoHS) | 8 | | |
| Classification (2014/53/EU, RE) | 1 | | |
| Basic UDI-DI | 4987669106G7 | | |

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 17, 2020 CE |
| COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances. | April 2, 2014 CE |
| Directive 2014/53/EU of the European Parliament and of the council on the market of radio equipment | August 4, 2017 CE |

Place: Aichi, Japan
Signed by

Effective date : October 21, 2021

Date of signature : October 18, 2021

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