

IDCP

EC DECLARATION OF CONFORMITY

We,

IDCP BV
Manuscriptstraat 12-14
1321 NN Almere
The Netherlands
SRN: NL-MF-000000755

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

IriScope (type number MEDL4R, Basic UDI-DI 87202991629MEDL4RGR)

having the intended purpose: The IriScope is intended to make images of the eye for eye diagnosis,

and have been classified as Class I, according to Annex VIII, Rule number 10, and the related software is classified as Class I according to Rule 11,

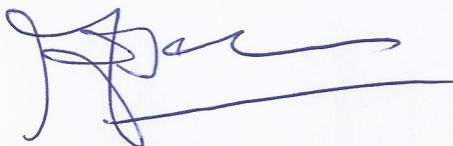
and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards EN 1041:2008 and EN ISO 15223-1:2016,

and comply to the requirements of EN 62471:2008 Photobiological safety of lamps and lamp systems to be classified **exempt** based on the exposure limit specified by Council Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC),

and are in conformity with the requirements of directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Signature:



Naarden, The Netherlands

Date: 9-2-2021

Name: Jan Boers

Function: Managing Director

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