

# Certificate of Compliance

We, the manufacturer, herewith declare that the device specified below is in compliance with the requirements of the following directives and standards:

## AUTO REF/KERATOMETER

Model: AR-910, ARK-910, AR-900, ARK-900

### Standards:

EN ISO 13485:2016, EN ISO 14971:2019,  
EN ISO 15223-1:2016, EN ISO 1041:2008+A1:2013  
EN 62366-1:2015, EN 62304:2006 + A1:2015,  
EN 60601-1:2006+A12:2014, EN 60601-1-2: 2015  
ISO 15004-1:2006, EN ISO 10342:2010,  
EN ISO 10343:2014, ISO 15004-2:2007

Manufacturer:

**Ningbo Ming Sing Optical R&D Co., Ltd.**  
No.365 Middle Jingu Road(west), Panhuo Street,  
Yinzhou District, Ningbo, Zhejiang Province, 315104,  
P.R.China

Date: 5th Jul, 2022

Signature & Stamp

*Amu*



EC Certificate Production Quality Assurance System: Certificate CN19/41105

The management system of

# Ningbo Ming Sing Optical R & D Co., Ltd.

No.702, North Tiantong Road, Yinzhou District, Ningbo, Zhejiang Province, 315192, P.R. China

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

For the following products

### AUTO REF/KERATOMETER

(Model : KR-9000, KR-9200, KR-9, KR-9300, RM-9000, RM-9200, AR-9, RM-9300, KR-9600, VX90, KR-9800, VX95, RM-9600, RM-9800),

### COMPUTERIZED VISION TESTER

(Model : CV-7000, CV- 7200, CV-7600, CV-7800, CV-7900, CV55, VX55, CV60, VX60, CV70, VX70)

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

This certificate is valid from 16 December 2019 until 12 November 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 05 April 2015 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/NGB/ 5756

Authorised by

## SGS Belgium NV, Notified Body 1639

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LPMD5008 - Certificate CE1639 AnnexV\_EN rev. 01

Page 1 of 1



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