Certificate Number CN18/41018

The quality 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

Facility identification number : F002889

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009
Canada:
Medical Devices Regulations – Part 1 SOR 98/282
United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D
For the following activities and devices

Design & manufacture of Auto REF/KERATOMETER, Computerized Vision Tester, Auto Chart Projector, Chart Monitor and Multi-function Auto Eye Testing Instrument used in the area of ophthalmology

This certificate is valid from
Effective Date: 2021-12-29 until Expiry Date: 2024-11-12
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2024-08-31
Issue 3. Certified since 2018-12-29

Authorised by LHenderson
Business Manager

L. Henderson

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SGS United Kingdom Ltd is an MDSAP authorised auditing organization

Digitally signed by Matei Andrei
Date: 2022.10.13 14:47:27 EEST
Reason: MoldSign Signature
Location: Moldova

SGS MDSAP 1116

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

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