

EU Quality Management System Certificate CN24/00005857

The management system of

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

SRN Number: CN-MF-000012092

has been assessed and certified as meeting the requirements of
**MDR (EU) 2017/745 Quality Management System certificate (Annex IX
Chapter I)**

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 31 October 2024 until 16 September 2029 and remains valid subject to satisfactory
surveillance audits.

Re certification audit due before 16 March 2029

Issue 3. Certified since 16 September 2024



Authorised by

Virginie Siloret

Global Medical Device

Certification Manager

SGS Belgium NV NB1639

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EU Quality Management System Certificate CN24/00005857,
continued

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



MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

Class IIa devices

MDA0309, MDS1009, MDS1010

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, ARK-900, AR-900, ARK-910, AR-910)
Basic UDI-DI: 69718214002V8

Multi-function Auto Eye Testing Instrument (Model: TR-8000, TR-8200, VX105)
Basic UDI-DI: 69718214005VE

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CN/NGB/5756 - S2A 1.3 + CTC

Authorized representative name and address (if relevant): Lotus NL B. V, Koningin Julianaplein 10, le Verd ,2595AA, The Hague, Netherlands

Previous certificate number: N/A

Change in between this certificate and previous one: models RM9200 & ARK900 shall be corrected with dash "-" by RM-9200 & ARK-900 as per LPMDREG5108 scope

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Certificate CN15/20435

The management system of

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design & manufacture of Auto Ref/Keratometer, Computerized Vision Tester, Auto Chart Projector, Chart Monitor, Multi-function Auto Eye Testing Instrument, Auto Non - Mydriatic Fundus Camera, Ophthalmic Unit and Auto Lensmeter used in the area of ophthalmology

This certificate is valid from 09 December 2025 until 12 November 2027 and remains valid subject to satisfactory surveillance audits.

Issue 9. Certified since 05 April 2015

L. Moran

Authorised by

Liz Moran
Business Manager

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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