

# CERTIFICATE

Number: 6124989

The management system of:

## Shanghai MediWorks Precision Instruments Co., Ltd.

No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District  
201100 Shanghai  
China

including the implementation meets the requirements of the standard:

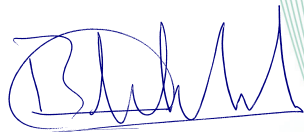
## ISO 13485:2016 EN ISO 13485:2016

### Scope:

Design, Development, Manufacture, Distribution, Installation and Servicing of Applanation Tonometers, Corneal Topographers, Vision Screeners, Three-dimensional Analysis Systems for the Anterior Eye Segment, Optical Biometers, Surgical Microscopes, Automatic Fundus Cameras, Hand-held Fundus Cameras, Retina Lens, Slit Lamp Microscopes, Portable Slit Lamps, Vision Charts in the area of ophthalmic monitoring or diagnosis

Certificate expiry date: 1 March 2026  
Certificate effective date: 28 March 2023  
Certified since: 28 March 2023

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director

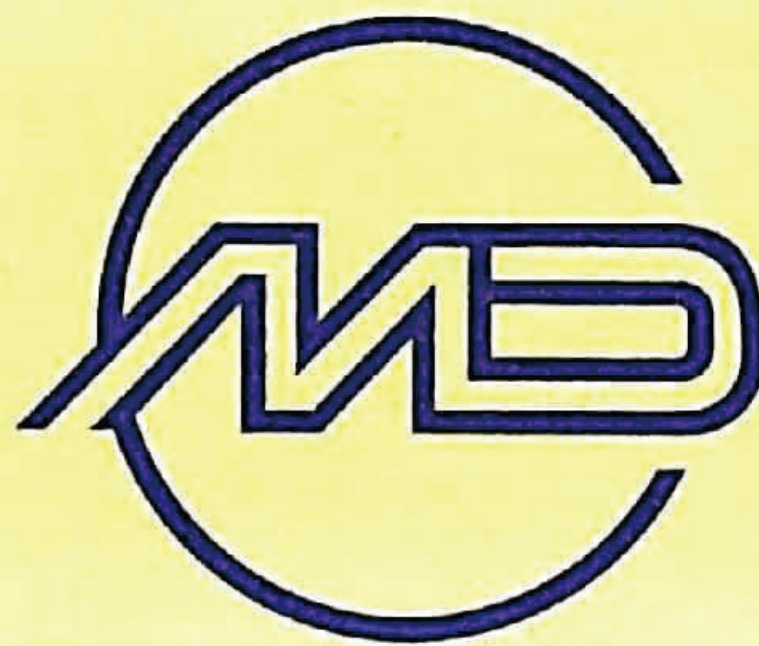


J.M.A. McKenzie  
Certification Manager

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REGISTRATION NO. 04717Q10000369

## **CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES**

This is to certify that the quality management system of

**Nanjing Redsun Optical Co., Ltd.**

**Registered Address: No.18 South of Xishangqiao Road of  
Nanjing City, Jiangsu, China.**

**Manufacturing Address: No.18 South of Xishangqiao Road of  
Nanjing City, Jiangsu, China**

Has been assessed and conformed to the following standard(s)

**YY/T 0287-2017 idt ISO 13485:2016**

The certificate is valid for the following scope:

**The Design, Development, Production and Service of Slit  
Lamp, Perimeter, Ophthalmic Ultrasound A/B Scan, Automatic  
computer perimeter, Fundus Camera, Handheld Slit Lamp.  
Phaco Emulsification, Operation Microscope, Auto  
Refractometer, Phoropter, Ophthalmic Laser and other machines.**

**Date of issue: October 20, 2021**

**Date of expiry: October 19, 2024**

General Manager:

**BEIJING HUA GUANG CERTIFICATION  
OF MEDICAL DEVICES CO., LTD.**

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)) or the website of CMD ([www.cmdc.com.cn](http://www.cmdc.com.cn)). Address: 5<sup>th</sup> floor of Zhong Lian building, No.1188, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



## EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Shanghai MediWorks Precision Instruments Co.,  
Ltd.

Midwest Ophthalmic Services  
Ballyloughane, Carrigkerry, Athea, Co.  
Limerick, Ireland.  
Tel: 069-76992

We, the manufacturer, herewith declare that the products

### Slit Lamp Microscopes and accessories

(Model/Type: S390L, S390H,  
S360DC, S350, S350S, S350C, S350DC, S280, S280S, S280CS360, S360S, S260, S260  
S, SL2, SL400L, SL400H, SL300L, SL300H, SL350H, SL350L, SL450L, SL450H)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shanghai MediWorks Precision Instruments Co., Ltd.  
Address: Zone A, 2<sup>nd</sup> Floor, No. 69, Lane 1985, Chunshen Road, Minhang District  
Shanghai, China

Shanghai, 12.12.2018  
Place, date

  
Legally binding signature, function



# NANJING REDSUN OPTICAL CO.,LTD.

ADD: 18-304 South of Xishangqiao Road of Yuhua Nanjing, China

TEL:0086-25-58575880

## DECLARATION OF CONFORMITY



We, the manufacturer:

Nanjing Redsun Optical Co.,Ltd.

NO.18 South of Xishangqiao Road of Nanjing,China. Tel:

0086-25-58575880

EU Representative: LUXUS LEBENSWELT GMB

Address: KOchstr.1, 47877, Willich, Germany

Declare under our sole responsibility that:

Product: Auto Refractometer

Model Name: AR7610

Product Group: Ophthalmic Equipment

Classification: Class I (in compliance with Annex VIII,RULE 1,, Medical Device

Regulation) Are in conformity with:

Essential Requirements of European Directive(s):

Medical Device Regulation (EU) 2017/745

Standard(s):EN60601-1:2006+A1:2013  
ISO9001:2008

Test report(s):TRS15060065  
ISO13485:2003

The compliance with the European Directive (2017/745C) is under the monitoring of the Notified Body:

For and behalf of  
NANJING REDSUN OPTICAL CO.,LTD.

Signature:Helen He

何亚琴

Export Sale  
Manager 2022-5-5

Authorized Signature