



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



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. IOL
Phaco Emulsification, Operation Microscope, Auto
Refractometer, Phoropter, Ophthalmic Laser, Tonometer.**

Date of issue: October 20, 2024

Date of expiry: October 19, 2027

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) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. Jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993