**Lot nr. 19 Autorefractometru , AR7610, RedSun Optical**

| *Specificarea tehnică deplină solicitată, Standarde de referinţă* | *Specificarea tehnică deplină oferita, Standarde de referinţă* |
|---|---|
| Autorefractometru Cod 170400.<br>Descriere Autorefractometru este un dispozitiv utilizat în timpul unui examen oftalmologic pentru a oferi o măsurare obiectivă a erorilor și de prescriptie de refractie a unei persoane pentru ochelari sau lentile de contact.<br>Parametru Specificație :Gama măsurilor de refracție<br>Distanța vertex, mm 0, 10, 12, 13.5, 15<br>Putere sferă (SPH) -25 ~ +25D (pasul 0,12/0,25D)<br>Putere cilindru(CYL) -10 ~ +10D (pasul 0,12/0,25D)<br>Axa 0-180º (pasul 1º);<br>Distanța pupilară, mm 10 - 85(pasul 1)<br>Diametru pupilar minim, mm 2,3;<br>Display LCD<br>Printer da;<br>Alimentare 220 V, 50 Hz | Autorefractometru Cod 170400.<br>Descriere Autorefractometru este un dispozitiv utilizat în timpul unui examen oftalmologic pentru a oferi o măsurare obiectivă a erorilor și de prescriptie de refractie a unei persoane pentru ochelari sau lentile de contact.<br>Parametru Specificație :Gama măsurilor de refracție Distanța vertex, mm 0, 10, 12, 13.5, 15<br>Putere sferă (SPH) -30 ~ +25D (pasul 0,12/0,25D)<br>Putere cilindru(CYL) -10 ~ +10D (pasul 0,12/0,25D)<br>Axa 0-180º (pasul 1º);<br>Distanța pupilară, mm 10 - 86(pasul 1)<br>Diametru pupilar minim, mm 2 mm;<br>Display LCD 7” touch screen<br>Printer da;<br>Alimentare 220 V, 50 Hz |

Digitally signed by Ceaicovschi Tudor
Date: 2022.09.15 12:40:16 EEST
Reason: MoldSign Signature
Location: Moldova

**NANJING REDSUN OPTICAL CO.,LTD.**

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

TEL:0086-25-58575880

# DECLARATION OF CONFORMITY

CE

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: AR-7610
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

Export Sale Manager 2022-5-5

Authorized Signature

## TECHNICAL INDEXES

New optical system, unique imaging impression

Hartman imaging analyzing and processing technology, accurate measurement result

TFT touch screen, can move front and back freely

Motorized chinrest

Manual focusing, auto measuring

Vertex Distance(VD): 0.0, 12.0, 13.75, 15.0

SPH：–30.00D~+25.00D（VD=12mm，0.01，0.06，0.12，0.25 Unit）

CYL：0.00D~±10.00D（0.06，0.12，0.25 Unit）

Axis(AX)：1° ~180° （1° Unit）

Cylinder Form：–，+，±

Puiple Distance(PD)：10~86mm

Minimum Pupil Diameter：2.0mm

Measuring Time：＜0.5s

Pupil Diameter：2.00–8.00mm

Measuring Light Energy：＜30uw（Insure measuring safety）

Radius of Curvature：5.0~10.0mm（0.01mm Unit）

Corneal Power：33.00D~67.00D

（In case that the corneal equivalent refractive power is 1.3375）

Corneal Astigmatism：0.00D~–15.00D（0.06D/0.12D/0.25D Unit）

Data Storing：Each 10 measured values of left eyes and right eyes

Axis：1° ~180°

Chart：Auto fog

Monitor：7″ TFT LCD touch screen (Angle of view adjustable)

Built–in Printer：57mm thermal printer

Electrical Power：AC 100~250V，50/60Hz

N.W.：16kg

G.W.：19.5kg

Dimensions(packing)：(L)650mm X (W)400mm X (H)620mm

# AR(K)7610

## Auto Refrac(Kera)tometer

# AR(K)7610

## Auto Refrac(Kera)tometer

**The most cost-effective**

**Hartmann refrac(kera)tometer in the world**

**Do what you want to do, save what you hope in time and money**

### Adjustable LCD Touch Screen

High brightness and contrast 7" wide color TFT LCD screen, smooth touch mode,different angle can be adjusted

### Motorized Chin Rest

By pressing the Up & Down buttons, the users can set and adjust the height of the patient's chin freely and quickly

### Data Record

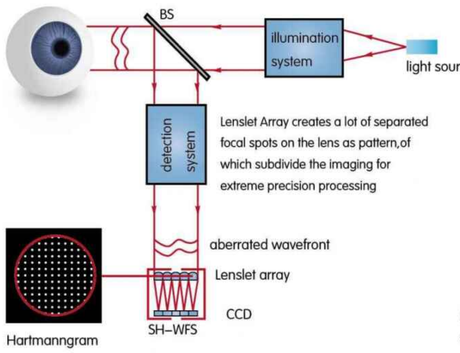
3 groups of data stored each measurement, maximum 10 groups of data can be stored

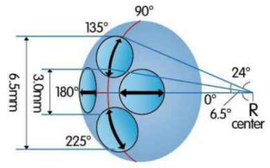
### Operation interface function

Intuitive icons provide the user an easier operating circumstances, and make the measurement become more convenient and the data to be measured more accurate and fast

### Professional Design

### Hartmann imaging processing technology




Measure peripheral keratometry precision of eyes with contact lenses fitting

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, 2019

Date of expiry: October 19, 2022

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: 010-67351993