

Anexa Nr. 11			
USG Oftalmologic (A-scan)			
<p align="center">Descriere:</p> <p align="center">USG oftalmologic care permite scanare cu ultrasunet unidimensional (A-scan) sau biometrie, care include măsurarea lungimii axiale a ochiului, adâncimea camerei anterioare, dimensiunile corpului vitros și grosimea cristalinelor a lentilelor.</p>			
Parametru		Specificația solicitată	Specificația oferită
Display	Color, LCD (inch)	≥ 7	6,5
	Touch Screen	da	da
Sonda	Frecvența, Mhz	≥ 10	10
	Raza scanării, mm	≥ 45	15~35mm
Diapazonul de scanare	Rezoluția, mm	± 0.1	0,01
	Rezoluția electronică, mm	± 0.03	$\pm 0,02$
Metoda	Imersie și Contact	da	da
IOL	formule min. 6 (SRK-II, SRK-T, Holladay, Hoffer-Q, Binkhorst-II, Haigis)	da	da
	Pașii de incrementare	0.25 D sau 0.50 D	da
Setările	Posibilitatea de selectare a tipului ochiului (drept, stâng)	da	da
	Tipul de selectare (Normal/Phakic, Dense Cataract, Silicone, Pseudo PMMA, Pseudo Silicone, Acrylic, Aphakic)	da	Phakic, Aphakic, Dense, various IOLs
	Măsurările (Axial length/AXL, Lens, AC/ACD, VCD/VITR)	da	Anterior chamber depth, lens thickness, vitreous body length, total length and average
Moduri de capturare	Manual și automat	da	da
Conexiuni externe:	USB - min. 2 porturi, USB pentru conexiunea cu PC	da	USB Port cu conexiune la PC
Raportul/Exportul imaginii și/sau a datelor	PDF, JPEG, PNG, GIF, TIFF, BITMAP	da	nu
Conectarea la printer	Prin PC și/sau printer propriu integrat	da	Printer integrat
Posibilitatea	Software upgrade De instalare ale altor sonde	da	da
	De înregistrare și stocare a datelor pacienților	da	da
	De a înregistra minim 3 utilizatori pentru lucru continuu cu DM	da	da
Alimentarea	220 V, 50 Hz	da	da
	Sondă pentru A-scan	da, 1 buc.	da, 1 buc.
	Geantă pentru transportare	da, 1 buc.	da, 1 buc.
	Troleu cu min. 5 roțile pentru DM cu platou de fixare al acestuia	da, 1 buc.	da, 1 buc.
Accesorii	Set de lucru pentru oftalmolog	da, min. 1 set	nu
	Calibrator	da, 1 buc.	da, 1 buc.
	Pedală	da, 1 buc.	da, 1 buc.
	Cablu de alimentare	da, 1 buc.	da, 1 buc.
	Hârtie	da, 15 buc.	da, 15 buc.

- 1.7Kg net weight, more portable.
- show actual value and deviation at the same time
- Sensitive , convenient, accurate and fast measurement
- The probe service life is long, high cost performance
- Point and surface point measurement display

calculate the calibration value of intraocular pressure (after achieving accurate intraocular pressure)

- Ultrasonic velocity and offset is adjustable, compare measuring results with other equipment easily.

Technology Parameter:

A Scan Biometer :

Probe Frequency: 10 Mhz

Resolution: 0.01mm

Accuracy: ±0.02mm

Gain adjustable: 0-120dB

Measurement range: 15~35 mm (vel 1640m/s)

Measurements: ACD, Lens, Vitreous, and AXL

Examination modes: Normal, Aphakic, pseudophakic and dense cataract.

Measurement mode: immersion and contact , auto and manual

IOL formulas: : SRK-II,SRK-T,BINKHORST,HOLLADAY,HOFFER-Q,HAIGIS

any of two groups can control display. Calculate IOL, DEM, DAM, REEF, etc.

And long term save 100 groups of measurement results of A scan.

Pachymeter:

Probe frequency: 20 Mhz

Resolution: 1um

Measurement range: 0.23~1.3mm

Accuracy: ±5um

Pachymeter measurement ways :

Single-point measurement

Five points measurement

Nine points measurement

Power requirement:

AC 100-240V 50-60Hz

Rate power: <= 45 VA

Dimension: 200*168*165(mm, L*W*H)

Weight of main unit: approx. 1.7kg (exclude the accessories)

SK-2000AP A Scan and Pachymeter



Models:

- SK-2000A A SCAN
- SK-2000P P SCAN
- SK-2000AP AP SCAN

You can buy separately as per you need

Feature

- 6.5"-inch color LCD touch screen, and user information can be easily input, more convenient and quick
- Light blue and white alternate design, select the user interface of the color matching, reduce the visual fatigue, protect your eyes.
- I - Station integrated workstation, complete data and waveform storage, report generation and printing function
- Rechargeable battery, could be used for 10 hours.
- Built-in thermal printer, A key print directly.
- USB port could connect your PC directly
- Support I-station workstation connection
- Small footswitch offer you good feeling.
- Six kinds language: Chinese, English, Russian, French, Spanish and Portuguese.

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000326476-PA-NA-CHN Rev.0.0

Project No.:
PRJN-176150-2019-PA-CHN

Valid Until:
27 May 2024

This is to certify that the quality system of:

Chongqing Sunkingdom Medical Instrument Co., Ltd.

No.1 XinMao Road (Free Trade Zone), BeiBei District, Chongqing, China

For design, production and final product inspection/testing of:

OPHTHALMIC ULTRASOUND EXAMINATION INSTRUMENT, APPLANATION TONOMETER

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 October 2020

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see
www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
10000326476-PA-NA-CHN Rev.0.0

Project No.:
PRJN-176150-2019-PA-CHN

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	06-10-2020

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Ultrasound Examination Instrument	SK-3000A, SK-2000AP	IIa
Applanation tonometer	SK-T, SK-Q, SK-R	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Chongqing Sunkingdom Medical Instrument Co., Ltd.	Legal Registered Address: No.1 XinMao Road (Free Trade Zone), BeiBei District, Chongqing, China
	Manufacturing Address: 35-2, Ying Tian Guang Dian Gong Gu, Cai Jia Gang Industrial Zone, BeiBei District, Chongqing, China

EU Representative

MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

Certificate No.:
10000326476-PA-NA-CHN Rev.0.0

Project No.:
PRJN-176150-2019-PA-CHN

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



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.ccaac.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.1488, An Ding Men West Street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-67351293