

Specificație Completată		
Dispozitivul Medical	Tonometru portativ ocular	
Modelul	Diaton ТГ/Дл - 03	
Țara de origine	Rusia	
Producătorul	АО «ГПИЗ»	
Tonometru ocular portativ		
Cod	170300	
Descriere	Tonometrul ocular este destinat pentru masurarea presiunii intraoculare	
Parametru	Specificația	Specificație completată
Tip	non-corneal	DA non-corneal
Autocalibrare	da	DA
Precizie	≤20mmHg +/-2mm ≥20mmHg- +/-10%	DA
Ecran	LCD	LCD
Alimentare	baterii	DA bateriei - durata de lucru pîna la 5000 de investigații

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 577120****Issued To:**

**Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

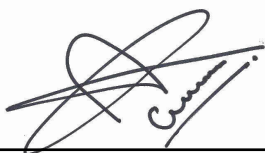
In respect of:

Manufacture, final inspection and test of intraocular pressure tonometers and magnetic field therapy devices.

Производство, выходной контроль и тестирование тонометров внутриглазного давления и аппаратов для магнитной терапии.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-06-27**

Date: **2019-02-07**

Expiry Date: **2021-11-07**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 577120**
 Date: **2019-02-07**
 Issued To: **Joint Stock Company "Ryazan State
 Instrument-Making Enterprise"
 32, Seminarskaya Str.
 390000, Ryazan
 Russian Federation**

Subcontractor:

Service(s) supplied

"Kasimov Instrument-Making Enterprise"-
 -Branch "Ryazan State Instrument-
 Making Enterprise"
 3, Industrialnaya Str.
 391300 Kasimov
 Russian Federation

Manufacture

Tonom GmbH
 Mergelberg 115 A
 48161 Münster
 Germany

EU Representative

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 577120**
Date: **2019-02-07**
Issued To: **Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

Date	Reference Number	Action
27 June 2016	8536503	First issue. Transfer from another Notified Body.
04 November 2016	8633374	Certificate Renewal
Current	8862697	Traceable to NB 0086.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Holds Certificate Number:

MD 577118

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture, installation, distribution and servicing of active medical devices for ophthalmology, magnetic field therapy and sterilizers.

Производство, инсталляция, продажа и сервисное обслуживание активных медицинских изделий для офтальмологии, магнитной терапии и стерилизаторов.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-23

Latest Revision Date: 2020-01-24

Effective Date: 2020-02-08

Expiry Date: 2023-02-07

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Certificate No: **MD 577118**

Location

Joint Stock Company
"Ryazan State Instrument-
Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Kasimov Instrument-Making
Enterprise-Branch Ryazan State
Instrument-Making Enterprise
3, Industrialnaya Str.
391300 Kasimov
Russian Federation

Registered Activities

Manufacture, installation, distribution and servicing of active medical devices for ophthalmology.

Производство, инсталляция, продажи и сервисное обслуживание активных медицинских изделий для офтальмологии.

Manufacture, installation, distribution and servicing of active medical devices for magnetic field therapy and sterilizers.

Производство, инсталляция, продажи и сервисное обслуживание активных медицинских изделий для магнитной терапии и стерилизаторов.



Original Registration Date: 2016-06-23

Latest Revision Date: 2020-01-24

Effective Date: 2020-02-08

Expiry Date: 2023-02-07

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Техническое задание на тонометр внутриглазного давления через веко цифровой портативный ТГДц-03

1. Тонометр внутриглазного давления через веко цифровой портативный ТГДц-03 предназначен для измерения тонометрического по Маклакову внутриглазного давления (ВГД) у детей и взрослых без применения анестезии.
2. Диапазон измерения тонометрического ВГД по Маклакову составляет от 5 до 63 мм рт. ст. Предел допускаемой погрешности измерения составляет ± 2 мм рт.ст. при измерениях в диапазоне от 5 до 26 мм рт.ст. включительно и $\pm 10\%$ - выше 26 мм рт.ст.
3. Проверка работоспособности тонометра производится на задатчике давления, входящем в комплект тонометра, при этом на дисплее отображается значение тестовой величины (26 ± 2) мм рт.ст.
4. По электробезопасности тонометр соответствует требованиям ГОСТ Р МЭК 60601-1-2010 и выполнен по степени защиты изделия типа В с внутренним источником питания.
5. Электропитание от двух элементов питания общим напряжением 3 В. Снижение напряжения электропитания до 2,55 В и ниже индицируется в виде символа "U".
6. Ток потребления не более 2 мА.
7. Средний срок службы не менее 5 лет.
8. Габаритные размеры тонометра (без футляра и задатчика давления) не более 176 x 26 x 20 мм.
9. Масса тонометра с элементами питания не более 105 г., без элементов питания не более 65 г. (без футляра и задатчика давления).
10. Тонометр обеспечивает 5000 циклов измерения без замены элементов питания.
11. Гарантийное срок эксплуатации тонометра 12 месяцев со дня продажи, если иное не указано в договоре (контракте).

Комплектность поставки тонометра

Наименование	Количество, шт.
Тонометр внутриглазного давления через веко цифровой портативный ТГДц-03	1
Устройство контроля работоспособности / задатчик давления	1
Футляр	1
Элемент электропитания VARTA AAA 1,5 V	2
Руководство по эксплуатации Часть I	1
Руководство по эксплуатации Часть 2	1
Памятка по обращению	1
Упаковка	I

Тонометр в футляре упаковывается в соответствии с требованиями ГОСТ Р 50444-92 и комплекта конструкторской документации предприятия-изготовителя в транспортную тару, в которую вкладывается упаковочный лист.

Anexa 27 Autorefractometru , Model: AR7610, Nanjing RedSun Optical

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

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: FR8900, AR-7610

Product Group: Ophthalmic Equipment
Classification: Class I (in compliance with Annex I&VII, Medical Device Directive)

Are in conformity with:

Essential Requirements of European Directive(s):
93/42/EEC Medical Device Directive (including 2007/47/EC)

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

Test report(s):TRS15060065
ISO13485:2003

The compliance with the European Directive (93/42/EEC) is under the monitoring of the Notified Body:

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

Signature:Helen He

Export Sale
Manager 2020-10-16

.....
Authorized Signature

AR7610 ARK7610 Auto refractometer



7" Color and touch screen,
Auto tracking ,
motorized chinrest ,
one key lock
IOL function
contact lens measure

Technical Data

New optical system, unique imaging impression
Hartman imaging analyzing and processing technology, accurate measurement result touch screen,
can move front and back freely

Motorized chinrest

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

SPH: -30.000~+25.000 (VD= 12mm, 0.01 , 0.06, 0.12, 0.25 Unit)

CYL: 0.000~± 10.000 (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

Pupil Diameter: 2.00-8.00mm

Measuring Light Ene (gy: <30L) w (Insure measuring safety)

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

Corneal Power: 33.000~67.000

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

Corneal Astigmatism: 0.000~ 15.000 (0.060/0 120/0 250 Unit)

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

Axis: 1 . ~ 180 .

Chart: Auto fog

Monitor: SHARP 7" TFT LCO touch screen (Angle of view adjustable)

Built-in Printer: 57mm thermal printer, auto paper-cutting

Electrical Powe : AC 100~250V, 50/60Hz

NW: 22kg

GW: 26.5kg

Dimensions(packing): (L)680mm X (W)400mm×(H)640mm

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



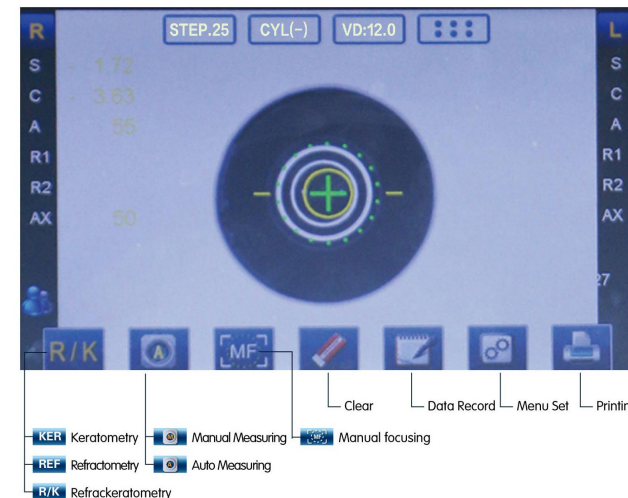
By pressing the Up & Down buttons, the users can set and adjust the height of the patient's chin freely and quickly

Data Record

DATA RECORD											
R	SPH	CYL	AX	L	SPH	CYL	AX	R	SPH	CYL	AX
1	-0.50	-1.50	95	1	-0.50	-1.25	99	1	-0.50	-1.25	99
2	-0.50	-1.50	95	2	-0.50	-1.25	99	2	-0.50	-1.25	99
3	-0.50	-1.50	95	3	-0.50	-1.25	99	3	-0.50	-1.25	99
4				4				4			
5				5				5			
6				6				6			
7				7				7			
8				8				8			
9				9				9			
10				10				10			
AVG	-0.50	-1.50	95	AVG	-0.50	-1.25	99				

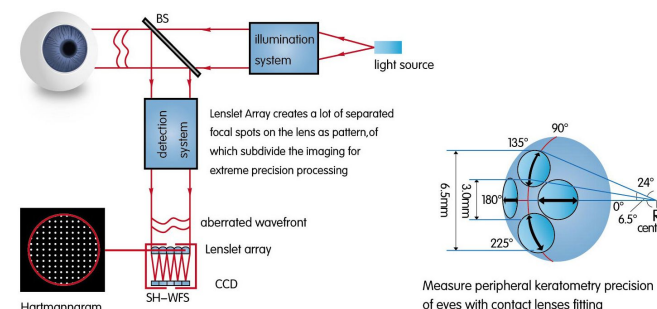
3 groups of data stored each measurement, maximum 10 groups of data can be stored

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

Hartmann imaging processing technology



Professional Design





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: 010-62351993