Anexa 1 Electrocardiograf cu 3 canale cu interpretare : MAC 600

Descriere: Electrocardiograf cu 3 canale, care înregistrează, printează şi/sau interpretează ECG de la o singură sau mai multe derivaţii simultan cu display color.
Tip pacient: adult, pediatric si neonatal
Numărul de canale de procesare: 3
Configuraţia: Portabil
Derivaţiile:
- Tip înregistrare: auto şi manual
- Sensivitatea: 2.5, 5, 10, 20 mm/mv
- Semnal de calibrare: da

Gama de frecvenţă:
- De filtrare: musculare, de frecvenţă înaltă, de frecvenţă joasă, de reţea 50 Hz

Impendanţa de intrare: ≥10 M Ohm cu fregventa de 10 Hz
Fregventa de analiza ECG: ≥500 sps
Rata de esantionare digitala: ≥2000 esan/sec/canal
Posibilitatea de conectarea la calculator cu soft specializat de la producator: Optional (sa prezinte denumirea softului si brosura);
Convertarea în format PDF: Optional (sa se indice capacitatea de ubgradare pe aceasta pozitie in brosura);
Indicator deconectare electrod acustic sau vizual: da
Imprimantă:
- Termică, încorporată
- Mărimea hîrtiei: ≥ 80 mm
- Să se indice numele derivaţiei printate: da
- Viteza de înscriere: 5, 12.5, 25 si 50 mm/s
- Derivaţiile înscrise: minim 12
- Numărul de derivaţii înscrise simultan: 3

Display:
- grafic, color
- Diagonala: ≥ 4.0 inch
- Tip: TFT LCD
- Rezolutia: 480 x 272
- Numărul de derivaţii afişate simultan: 12

Posibilitatea transmiterii datelor la un sistem de management al datelor EKG: prin fir (să se indice interfaţa te transmitere);
Date pacient: Nume, ID, vîrsta, sex, greutate, înălţimea;
Măsurări: PR, PQ, QT, QTC, P, QRS, T, HR;
Interfaţa de control: Limbile prezente obligatoriu: Romina, Rusa si engleza
Identificarea aritmiei: da
Interpretarea: da
Timpul interpretării: minim 10 s
Alimentarea- 220 V, 50 Hz
Baterie internă- reîncărcabilă
Timp operare autonomă: ≥5 h fara printare dar cu anliza si monitoring pe display / ≥ 1,3 h de printare continu a ritmului cu viteza 25mm/s.
Protecţie defibrilator-da
Indicatori vizuali:
- contact slab sau lipsă de contact
- status sistem
- deconectare alimentare reţea
- baterie descărcată

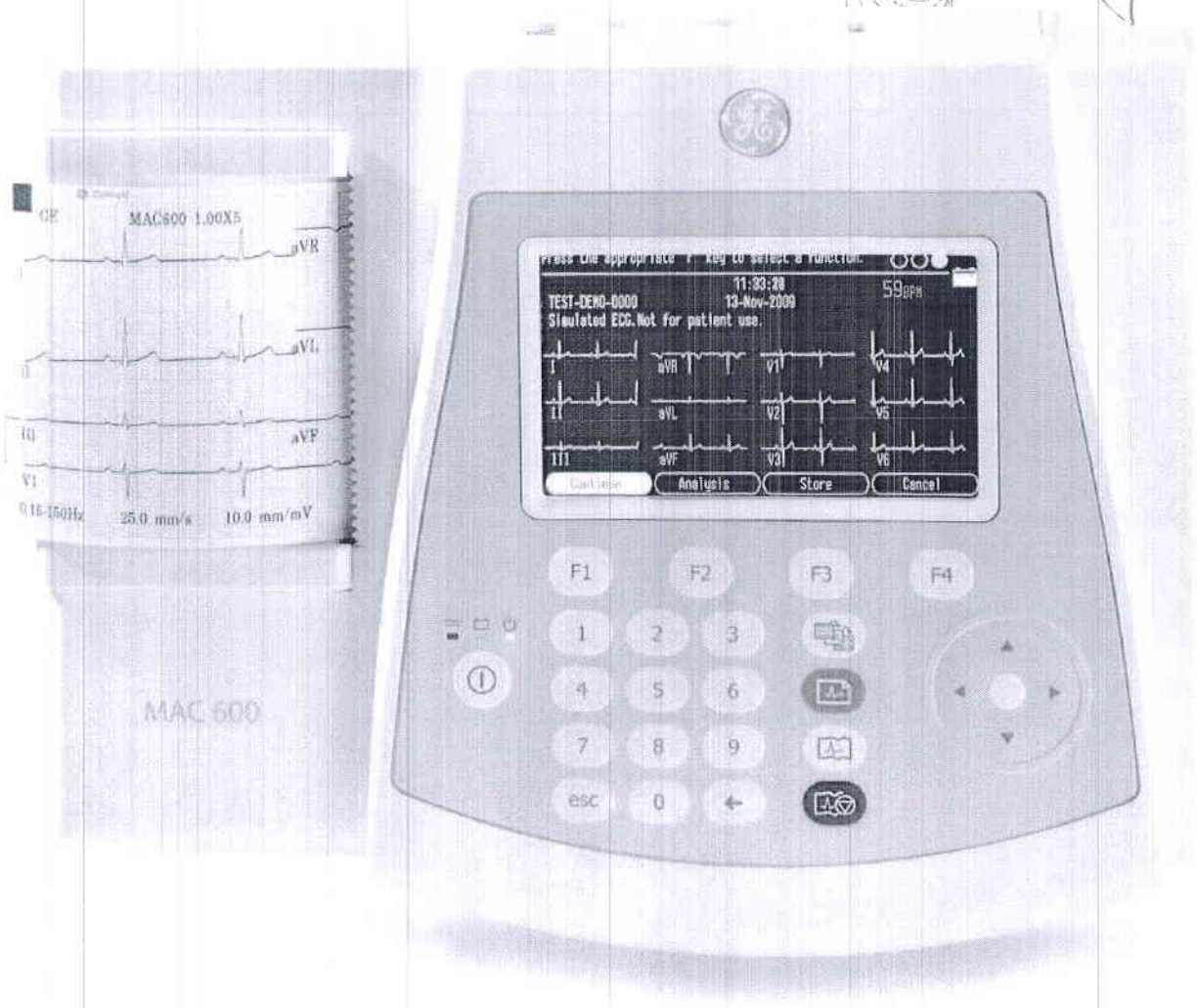
Accesorii standard:
Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) şi membranari de tip cleşte (4 buc.) – 1 set;
Hîrtie termică- 1 bucata;
Gel de contact- 250 gr.
Geantă pentru transportare - 1 unit.

Termenul de garantie 24 luni

GE Healthcare

MAC® 600 Resting ECG

Technical Specifications



Instrument Type	
Microprocessor augmented automatic electrocardiograph; 10-leadwire, 12-lead simultaneous acquisition with programmable lead configuration.	
Processing	
ECG interpretation:	Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics
Computerized measurements:	12-lead analysis
ECG analysis frequency:	500 samples/second (sps)
Digital sampling rate:	2,000 samples/second/channel
ECG on-screen preview:	On-screen preview of acquired 10-second ECG waveform and optional 12SL measurement and interpretation
Acquisition mode:	Pre-acquisition or post-acquisition, provide 10 seconds of instantaneous ECG acquisition
Dynamic range:	AC Differential ± 5mV, DC offset ±300 mV
Resolution:	4.88 µV/LSB @ 500 sps
Frequency response:	–3 dB @ 0.01 to 150 Hz
Low cut-off frequency:	0.01 Hz, 0.02 Hz, 0.16 Hz or 0.32 Hz (-3 dB limits)
High cut-off frequency:	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
High cut-off frequency:	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Adaptive AC filter:	47 Hz to 53 Hz when set to 50Hz, 57 Hz to 63 Hz when set to 60 Hz
Common mode rejection:	>100 dB (with AC filter switched on)
Input impedance:	>10MΩ @ 10 Hz, defibrillator protected
Patient leakage:	<10 µA
Special acquisition functions:	Disconnected lead detection except RL, excessive AC noise, baseline wander and muscle tremor messages
Heart rate meter:	30 to 300 BPM ±10% or ±5 BPM, whichever is greater. Heart rates outside this range will not be displayed
Start-up time:	Less than 7 seconds
Patient Information	
Supported patient information:	Patient ID, secondary ID, age, date of birth, gender. Alphanumeric entry in T9 type for patient ID and secondary ID.
Display	
Display type:	4.3 inch (110 mm) diagonal, TFT LCD with LED graphics backlit (color optional)
Display resolution:	480 X 272 pixels with scrolling waveform
Display data:	Heart rate, patient ID, clock, battery power indicator, waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, prompts. 12-leads standard display.
Writer	
Writer technology:	Thermal dot array
Writer speed:	5, 12.5, 25, & 50 mm/s
Number of traces:	3 leads + 1 rhythm or 3 leads; user selectable
Writer sensitivity/gain:	2.5, 5, 10, 20, 10/5 (split calibration) mm/mV
Writer speed accuracy:	±5%
Writer amplitude accuracy:	±5%
Writer resolution:	Horizontal 40 dots/mm @ 25 mm/s, 8 dots/mm vertical
Paper type:	Thermal, Z-fold perforated, 80 mm width, 280 sheets/pack. Roll paper 15.7 m.
Keyboard	
Type:	Type Membrane keyboard with tactile feedback
Software Standard	
Resting ECG mode:	Records and prints 12-lead resting ECGs with 10-second duration as a standard feature
Hookup Advisor™:	Provides visual indication of signal quality
Multi-language support:	Supports 16 languages
Software Options	
Measurement:	Supports measurement with Marquette 12SL ECG Analysis Program
Measurement and interpretation:	Supports measurement and interpretation with Marquette 12SL ECG Analysis Program
Color:	Color display

External storage:	200 ECGs in external memory (SD card)
Transmission:	ECG data transmission via serial cable
XML format:	ECG storage in XML format
PDF format:[1]	ECG storage in PDF format
Communication (optional)	
MUSE® Cardiology Information System Compatible	
Serial cable:	ECG transmission to MUSE Cardiology Information System
Serial cable:	ECG transmission in XML format
SD card interface:	Compatible with MUSE v7
CardioSoft™ Interface	
SD card interface:	Compatible with Cardiosoft V6.51
Storage (optional)	
ECG storage format:	GE storage format for MUSE and CardioSoft. XML storage format. PDF storage format.
PDF file name format:	User-configurable file name, which includes patient ID, secondary ID, date of birth, ECG recording date and time
Report Formats	
Thermal printer report formats	4 by 2.5s 4 by 2.5s + 1 rhythm lead 4 by 3s 4 by 10s Autorhythm (10-second ECG data for 3 leads) Printing of 4 by 10s or Autorhythm for abnormal ECG Continuous 3-channel rhythm
PDF report format (A4 format):	4 by 2.5s 4 by 2.5s + 1 rhythm lead 2 by 5s 2 by 5s + 1 rhythm lead 2 by 5s @ 50mm/s 4 by 10s Autorhythm (12-lead)
Accessories	
IEC/AHA leadwire and electrode adaptor sets (user-selectable) 10-lead patient cable (user-selectable replaceable leads or fixed leads cables) Electrodes (disposable or reusable, user-selectable) Country-specific power cords Z-fold and Roll paper Electrode cream 250 ml/tube	
Electrical	
Power supply:	External AC/DC adaptor or battery operation
External Adaptor Specifications	
Input voltage:	100 to 240 VAC ±10%
Input current:	Maximum 0.6A @ 90 VAC, 0.3A @ 240 VAC
Input frequency:	50 to 60 Hz ± 3Hz
Output voltage:	12V ± 5%
Battery Specifications	
Battery type:	Replaceable and rechargeable, Lithium Ion
Battery capacity:	7.2V typical, 2.25 AH ±10% 360 minutes of continuous operation without recording or 250 ECGs in 2.5 X 4 format at 25 mm/S and 10 mm/mV or 100 minutes continuous rhythm print at 25 mm/S and 10 mm/mV.
Battery charge time:	Approximately 3 hours from total discharge (with display off)
Physical Specification	
Height:	81 mm
Width:	263 mm
Depth:	208 mm
Weight:	1.2 Kg including battery, without paper

[1]ECG storage in PDF format is not supported in Russian language.

Environmental Specification	
Temperature	
Operating	5°C to 40°C
Transport/storage:	-15°C to 50°C
Humidity	
Operating:	25% to 95% RH non-condensing
Transport/storage:	25% to 95% RH non-condensing
Pressure	
Operating:	700 to 1060 hPA
Transport/storage:	500 to 1060 hPA
Certification	
Class II, type CF defibrillator proof UL 60601-1 Medical Electrical Equipment, part 1: General Requirements for Safety CAN/CSA C22.2 No. 601.1 General Requirements for Safety CE marking for Council Directive 93/42/EEC concerning medical devices IEC 60601-1 General Requirements for Safety IEC 60601-1-1 General Requirements for Safety Medical Electrical systems IEC 60601-2-25 Particular Requirements for the Safety of Electrocardiographs IEC 60601-2-51 Particular Requirements for Safety, including essential performance, of recording and analyzing single channel and multi channel electrocardiographs IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility IEC 60601-1-4 General Requirements for Safety – Programmable electrical medical systems IEC 60601-1-6 General Requirements for basic safety and essential performance – Collateral Standard: Usability-Edition 2.0 Meets applicable AAMI EC-11 requirements and AAMI EC 13 (Clause 4.2.7 only)	

GE Healthcare
Munzinger Straße 5
79111 Freiburg, Germany
Tel. +49 761 4543 0 • Fax +49 761 4543 233

www.gehealthcare.com

GE imagination at work

EMEA 2050698-002/0210

LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION/ *CERTIFICATE* **N° 7550 rev. 16**
Délivrée à Paris le 1er juin 2018
Issued in Paris on June 1st, 2018

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité / *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificate CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant (nom et adresse) / *Manufacturer (name and address)*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
A General Electric Company, part of the GE Healthcare organization
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 - USA

Catégorie du(des) dispositif(s) / *Device(s) category*

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients
Voir addendum
Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems
See addendum

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P178961-2, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.
LNE/G-MED certifies that, on the basis of the results contained in the file referenced P178961-2, the quality system - for design, manufacturing, and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une verification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date* : **June 8th, 2018 (included)**
Valable jusqu'au / *Expiry date* : **June 7th, 2021 (included)**

Laboratoire national de métrologie et d'essais • LNE

On the behalf of the Certification Director
Béatrice LYS
G-MED Certification Technical Director

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Addendum à l'attestation N° 7550 rev. 16
Addendum of the certificate N° 7550 rev. 16
Dossier / *File* N° P178961-2

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Produit *Product* Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Patient monitor, Central unit	Central Station (CSCS)	IIb
Patient monitor module, multiparameter	Patient Data Module (PDM)	IIb
Patient monitoring system, general physiology, single patient	B850	IIb
Patient monitor, multiparameter	B20	IIb
Patient monitor, multiparameter	B40	IIb
Patient Monitor, multiparameter	B105	IIb
Patient Monitor, multiparameter	B125	IIb
Patient Monitor, multiparameter	CARESCAPE ONE	IIb
Transportable physiologic monitoring system	V100	IIb
Patient monitor , central unit	CIC Pro	IIb
Telemetry system, electrocardiograph	ApexPro Telemetry System	IIb
Clinical monitoring systems	Unity Network ID	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	MacLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	CardioLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	ComboLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	Special Lab	IIb
Electrocardiograph, Holter analyzer	Mars	IIa
Electrocardiograph, Holter analyzer	Mars SP4	IIa

Laboratoire national de métrologie et d'essais · LNE

LNE/G-MED | 0459

On the behalf of the Certification Director
Béatrice LYS
G-MED Certification Technical Director

720 DM 0701-31 rev 5 du 28/07/2015

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
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1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Produit *Product* Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Information system software, application program, cardiology	MUSE – SW Only	IIa
Information system software, application program, cardiology	CV Web	IIa
Interpretive multichannel electrocardiograph	MAC 5500	IIa
Interpretive multichannel electrocardiograph	MAC 5500 HD	IIa
ECG Acquisition module	CAM 14V2	IIa
ECG Acquisition module	CAM HD	IIa
Interpretive multichannel electrocardiograph	MAC 3500	IIa
Interpretive multichannel electrocardiograph	MAC 2000	IIa
Interpretive multichannel electrocardiograph	MAC 1600	IIa
Interpretive multichannel electrocardiograph	MAC i	IIa
Interpretive multichannel electrocardiograph	MAC 800	IIa
Interpretive multichannel electrocardiograph	MAC 600	IIa
Interpretive multichannel electrocardiograph	MAC VU360	IIa
Stress exercise monitoring system, cardiac	Case	IIa
Stress exercise monitoring system, cardiac	Cardiosoft / CS	IIa
Stress exercise monitoring system, cardiac	Cardiosoft /CS WIN8	IIa
Electrocardiograph, Electrodes	KISS	IIa

LNE/G-MED 0459

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Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Accessoires *Accessories* Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Electrode Pair Responder Internal	**2030249-001**	**IIb**
Contact Paddle, Internal, Adult	**38401319**	**IIb**
Contact Paddle, Internal, Child, 1 Pair	**38401320**	**IIb**
Contact Paddle, Internal, Infant, 1 Pair	**38401321**	**IIb**

Identification du site couvert et des activités / *Identification of location and activities*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC - 8200 WEST TOWER AVENUE - MILWAUKEE, WISCONSIN 53223 - USA
Siège social – responsable de la mise sur le marché
Conception, fabrication et contrôle final
Headquarters – legal manufacturer
Design, manufacture and final control

LNE/G-MED 0459

Laboratoire national de métrologie et d'essais • LNE

On the behalf of the Certification Director
Béatrice LYS
G-MED Certification Technical Director

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Anexa 2. Tonometru ocular digital TGD-01

Limita erorii de măsurare admisă în intervalul:
de la 5- 20 mmHg +/-2,0mmHg;
de la 20-60 mmHg+/-10%;
Timpul de măsurare 3-5 secunde;
Alimentarea 3- V;
Baterie – AAA;
Numărul de cicluri de măsurare pe un set de bateri, nu mai mic de 1500,
Greutatea 90-100 grame;
Dimensiuni totale 170 X 25x 20 mm.

Termenul de garantie 24 luni

Техническое задание на тонометр внутриглазного давления через веко цифровой портативный ТГДц-01

Тонометр внутриглазного давления через веко цифровой портативный ТГДц-01 "ПРА" предназначен для измерения **истинного** внутриглазного давления (ВГД) у детей и взрослых без применения анестезии.

1. Диапазон измерения ВГД с цифровым отображением на дисплее от 5 до 60 мм рт. ст.

Предел допускаемой погрешности измерения ВГД в диапазоне от 5 до 20 мм рт.ст. ± 2 мм рт. ст., а в диапазоне от 20 до 60 мм рт.ст. - ± 10 %.

2. Время одного измерения ВГД, с, не более - 3.

3. При отклонении тонометра от вертикали на угол от (4,5±1,5)° до (45±5)° звучит прерывистый звуковой сигнал. Звуковой сигнал не звучит при отклонении тонометра от вертикали на углы менее 3° и более 50°.

4. В комплекте имеется тест-устройство (задатчик давления) для проверки работоспособности тонометра.

5. По электробезопасности тонометр соответствует требованиям ГОСТ Р 50267.0-92 и выполнен по степени защиты изделия типа В с внутренним источником питания.

6. Напряжение электропитания, В - 3.

7. Тип элемента питания - CR2032

8. Ток потребления, мА, не более - 1.

9. Количество циклов измерения на одном элементе питания, не менее - 1500.

10. Имеется индикация разряда элемента питания.

11. Средний срок службы, лет, не менее - 5.

12. Габаритные размеры, мм, не более - 173,5 х 25,5 х 19,5.

13. Масса, г, не более – 89, без элемента питания - 75.

14. Поверка тонометра осуществляется один раз в год в соответствии с методикой поверки тонометра БИРМ.941329.003МП региональным Центром стандартизации и метрологии в установленном порядке, а сведения о поверке заносятся в таблицу.

15. Комплектность средства измерений

Наименование	Количество, шт.
Тонометр внутриглазного давления ТГДц-01 «ПРА»	1
Колпак	1
Устройство контроля работоспособности	1
Элемент электропитания	1
Лазерный диск с учебным фильмом	1
Руководство по эксплуатации	2 части
Памятка по обращению	1
Упаковка	I
Отвертка	1
Методика поверки БИРМ 941329.003МП	1

16. Гарантийное обслуживание 24 месяца.

17. Постгарантийное обслуживание.

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By Royal Charter

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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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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Anexa 3.Dulap de sterilizare GP-40MO

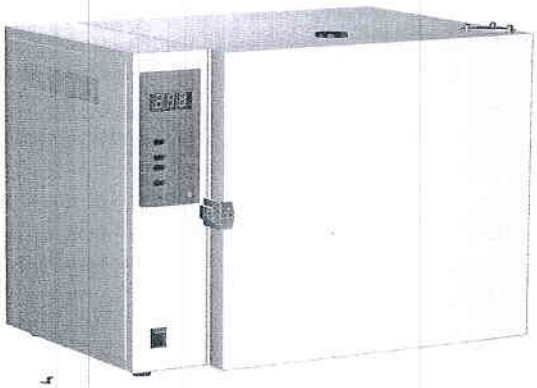
Descriere: Sterilizator cu aer uscat destinat sterilizării intrumentelor medicale cu consctrucție interioară din oțel inox.
Specificația: Ventilație forțată, controlată electronic.
Construcție interioară -oțel inox.
Construcție exterioară cu acoperire anticorozivă.
Regimuri de sterilizare programabile.
Protecție la supraîncălzire analogical digitală.
Alarma vizuală. Volumul 40 l.
Camera sterilizatorului-Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior.
Temperatura-50 - 200°C.
Abaterea temperatură nu mai mare de 3°C.
Setarea timpului 1 - 999 min.
Abatere timp.≤ 1 min.
Timp de încălzire pînă la 180°C.≤48 min
Regim de sterilizare prestabilite: 180°C,/60 min ; 160°C/150 min; 120°C/45 min
Timpul de răcire ≤ 35 min, pînă la 75°C.
Deconectare de avariere la temperatura 205 - 235°C.
Tipul de funcționare fără întrerupere 16 ore.
Rafturi 2, din oțel inox.
Cerințe de alimentare la rețeaua electrică: 200-240V, 50 Hz.
Termenul de garantie 24 luni

Anexa 4. Dulap de sterilizare GP-80MO

Descriere: Sterilizator cu aer uscat destinat sterilizării intrumentelor medicale cu consctrucție interioară din oțel inox.
Specificația: Ventilaţie forţată, controlată electronic.
Construcție interioară -oțel inox.
Construcție exterioară cu acoperire anticorozivă.
Regimuri de sterilizare programabile.
Protecție la supraîncălzire analogical digitală.
Alarma vizuală.
Volumul 80 l. Camera sterilizatorului-
Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior.
Temperatura-50 - 200°C.
Abaterea temperatură nu mai mare de 3°C.
Setarea timpului 1 - 999 min.
Abatere timp.≤ 1 min.
Timp de încălzire pînă la 180°C.≤ 55 min
Regim de sterilizare prestabilite: 180°C,/60 min ; 160°C/150 min; 120°C/45 min
Timpul de răcire 50 min, pînă la 75°C.
Deconectare de avariere la temperatura 205 - 235°C.
Tipul de funcționare fără întrerupere 16 ore.
Rafturi 2, din oțel inox.
Cerinţe de alimentare la reţeaua electrică: 200-240V, 50 Hz
Termenul de garantie 24 luni

СТЕРИЛИЗАТОРЫ ВОЗДУШНЫЕ

ГП- 10 МО, ГП- 20 МО
ГП- 40 МО, ГП- 80 МО



Стерилизаторы воздушные предназначены для стерилизации хирургических инструментов, стеклянной посуды и термостойких шприцев (с отметкой 200°С) и игл к ним. Стерилизаторы могут быть использованы для дезинфекции и сушки медицинских изделий.

Исполнение:

– с опосредованным охлаждением стерилизуемых изделий внутри камеры,

– с естественным охлаждением стерилизуемых изделий внутри камеры.

ОСНОВНЫЕ СВОЙСТВА:

– в стерилизаторах с опосредованным охлаждением применяется дополнительная воздушная рубашка вокруг камеры, система охлаждения работает без подачи холодного воздуха на стерилизуемый материал внутри камеры;

– автоматическая регулировка и поддержание температуры;

– вся необходимая информация о режимах работы и выбранной программе отображается на цифровом дисплее;

– энергонезависимая память для сохранения параметров до 10 программ, которые можно изменять и вызывать для работы;

– равномерное распределение температуры по объему камеры;

– электронные процессорные блоки управления изготавливаются на высококачественном импортном оборудовании с использованием технологии поверхностного монтажа, на основе импортной элементной базы;

– стерилизаторы оснащены высококачественными, надежными электровентиляторами, что исключает поломки и сводит к минимуму затраты на гарантийное и послегарантийное обслуживание;

– устройство защиты от перегрева;

– современный дизайн;

– малое энергопотребление;

– камера и все элементы, контактирующие со стерильным инструментом, выполнены из качественной нержавеющей стали.


СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р
ГОССТАНДАРТ РОССИИ

СЕРТИФИКАТ СООТВЕТСТВИЯ


РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Наименование	ГП-10МО	ГП-20МО	ГП-40МО	ГП-80МО
Объем камеры, л	10	20	40	80
Габаритные размеры, (ШхГхВ) мм, не более	440x450x415	625x450x415	705x510x495	815x580x595
Внутренние размеры, (ШхГхВ) мм, не более	150x225x275	330x220x275	410x280x355	520x350x455
Мощность, кВт, не более	1,0	1,3	1,8	2,0
Масса, кг, не более	20	21(24)*	26(31)*	37(43)*
Задаваемые температурные режимы, °С	60...200	60...200	60...200	60...200
Время нагрева стерилизатора до температуры +180°С, мин, не более	30	35	48	55
Задаваемое время выдержки, мин	1...999	1...999	1...999	1...999
Время охлаждения до температуры +75°С, мин, не более*	35	35	35	50
Автоматическая остановка процесса стерилизации при отклонении температуры от заданной, °С, не более	±3	±3	±3	±3
Аварийное отключение стерилизатора от сети при перегреве в камере, °С	205...235	205...235	205...235	205...235
Количество полок стандартное/макс., шт.	2 (4)	2 (4)	2 (4)	2 (4)
Время непрерывной работы в сутки, ч, не более	16	16	16	16
Питание, В/Гц	220/50	220/50	220/50	220/50

Фиксированные программы установленные на заводе: 180°С/60мин, 160°С/150мин, 120°С/45мин, 85°С без отсчета времени

* стерилизаторы с опосредованной системой охлаждения.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 15 июня 2015 года № ФСР 2011/10267

На медицинское изделие
Стерилизаторы воздушные ГП-5 МО, ГП-10 МО, ГП-20 МО, ГП-40 МО, ГП-80 МО по ТУ 9451-026-41457390-2011

Настоящее регистрационное удостоверение выдано
Акционерное общество "Государственный Рязанский приборный завод" (АО "ГРПЗ"), Россия, 390000, г. Рязань, ул. Семинарская, д. 32

Производитель
Акционерное общество "Государственный Рязанский приборный завод" (АО "ГРПЗ"), Россия, 390000, г. Рязань, ул. Семинарская, д. 32

Место производства медицинского изделия
АО "ГРПЗ" - филиал "Касимовский приборный завод", 391300, Рязанская обл., г. Касимов, ул. Индустриальная, д. 3

Номер регистрационного досье **№ РД-7239/14221 от 26.05.2015**

Вид медицинского изделия **173090**

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции для медицинского изделия **94 5120**

КОПИЯ ВЕРНА

Отдел сбыта

приказом Росздравнадзора от 15 июня 2015 года № 4077 допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0012194

ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Акционерное общество «Государственный Рязанский приборный завод» (АО «ГРПЗ»)

наименование организации или фамилия, имя, отчество индивидуального предпринимателя, принявших декларацию о соответствии

Зарегистрировано Межрайонной инспекцией Федеральной налоговой службы № 2 по Рязанской области, дата регистрации 20.12.2011 , ОГРН: 1116234013598

сведения о регистрации организации или индивидуального предпринимателя (наименование регистрирующего органа, дата регистрации, регистрационный номер)

Адрес: РОССИЯ, Рязанская область, 390000, г. Рязань, ул. Семинарская, д.32, телефон: (49131) 27026, E-mail: root@kaspz.ru

адрес, телефон, факс

в лице директора АО «ГРПЗ» - филиал «Касимовский приборный завод» Караваева Валерия Михайловича

(должность, фамилия, имя, отчество руководителя организации, от имени которой принимается декларация)

заявляет, что Стерилизаторы воздушные ГП-5 МО, ГП-10 МО, ГП-20 МО, ГП-40 МО, ГП-80 МО, ТУ 9451-026-41457390-2011

(наименование, тип, марка продукции, на которую распространяется декларация,

Серийный выпуск, Код ОКПД 2 32.50.12.000, Код ТН ВЭД 8419200000

сведения о серийном выпуске или партии (номер партии, номера изделий, реквизиты договора (контракта), накладная , код ОК 005-93 и (или) ТН ВЭД ТС или ОК 002-93 (ОКУН), номер и дата договора или контракта о поставке продукции

Изготовитель: Акционерное общество «Государственный Рязанский приборный завод» (АО «ГРПЗ»), Адрес: РОССИЯ, Рязанская область, 390000, г. Рязань, ул. Семинарская, д.32, Место производства медицинского изделия: АО «ГРПЗ» - филиал «Касимовский приборный завод» 391300, Рязанская область, г. Касимов, ул. Индустриальная, д.3, телефон: (49131) 27026, E-mail: root@kaspz.ru

наименование изготовителя, страны и т.п.))

соответствует требованиям ГОСТ Р 50444-92; ГОСТ 12.2.091-2012; ГОСТ Р МЭК 61326-1-2014; ГОСТ IEC 61010-2-010-2013

(обозначение нормативных документов, соответствие которым подтверждено

данной декларацией, с указанием пунктов этих нормативных документов, содержащих требования для данной продукции)

Декларация принята на основании: Сертификат системы менеджмента качества ISO 13485:2012 № MD 577118, выданный Акционерному обществу «Государственный Рязанский приборный завод», Регистрационное удостоверение на медицинское изделие от 15 июня 2015 года № ФСР 2011/10267, выдано Федеральной службой по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

(информация о документах, являющихся основанием для принятия декларации)

Дата принятия декларации 16.02.2018

Декларация о соответствии действительна до 15.02.2021

М.П. КАСИМОВСКИЙ ПРИБОРНЫЙ ЗАВОД

(подпись) Валерий Михайлович Караваев

(инициалы, фамилия)

Сведения о регистрации декларации о соответствии

Регистрационный номер RA.RU.11АБ69, Орган по сертификации Общества с ограниченной ответственностью "ЛенСерт"

(наименование и адрес органа по сертификации, зарегистрировавшего декларацию)

адрес: 195027, РОССИЯ, город Санкт-Петербург, Пискарёвский проспект, 2, корпус 3, литер А, офис 852, 854

Регистрационный номер декларации о соответствии РОСС RU.АБ69.Д03329, от 16.02.2018

(дата регистрации и регистрационный номер декларации)

М.П. Г.А. Вагер

(подпись, инициалы, фамилия руководителя органа по сертификации)

КОПИЯ ВЕРНА

Anexa 5. Centrifuga EBA 200

Caracteristici generale: Centrifugă pentru volume mici de probă. Centrifuga este livrată cu rotor unghiular cu 8 locuri pentru eprubete de 15 ml. Ideală pentru aplicații în medicină. Poate fi utilizată cu o serie de eprubete. Utilizarea cu eprubete din sticlă fără folosirea adaptoarelor. Adaptoare pentru eprubete de colectare a sîngelui sunt disponibile la cerere.

Specificații tehnice:

- ***Capacitate maximă*** Rotor unghiular 8 x 15 ml
- ***RPM max*** 6,000 min-1
- ***RCF Max*** 3,461
- ***Dimensiuni (Î x L x A)*** 228 x 262 x 352 mm
- ***Greutate*** Aproximativ 8 kg
- ***Răcire*** Răcire cu aer
- ***Rotor*** Inclus, rotor unghiular pentru 8 x 15 ml eprubete

Termenul de garantie 24 luni

Hettich
CENTRIFUGES

EBA 200

BLOOD / URINALYSIS / PEDIATRIC

Press 'Start' in Case of Emergency

High-performance with built-in 8-place rotor, compact frame and all-metal containment for added safety. Ideal for blood, urine and pediatric tubes. STAT, PPP and coag. in minutes with the EBA 200 S model.

MAX. CAPACITY	8 x 15 mL
MAX. RPM/RCF	8,000/6,153

QUIET OPERATION
Quiet as a normal conversation. Will not increase noise levels or contribute to distractions.

FUNCTIONAL DESIGN
Easy to lift lid with front-facing control panel for effortless interaction and programming.

ENHANCED SAFETY
Self-closing, auto-locking lid with steel latches. All-metal chamber provides reinforced security.

FIVE YEAR WARRANTY
All Hettich centrifuges are protected by our 5-year warranty and full technical support.

FULLY CERTIFIED
Engineered and manufactured in accordance with all relevant safety and production standards.

MADE IN GERMANY
German engineered and manufactured to be quiet, reliable and safe since 1904.

DIMS. (HxWxD): 9.0" x 10.3" x 13.9"

→ **hettweb.com/eba200**

HETTICH EBA 200 APPLICATION PACKAGES

↓

EBA 200 **BLOOD TUBE** PACKAGE - 8

Tube Qty.	Volume (mL)	Size (mm)	200 RPM	200 S RPM	200 RCF	200 S RCF	PKG. NO. (EBA 200)	PKG. NO. (EBA 200 S)
8	1.6 - 5	13 x 75	≤ 6,000	≤ 8,000	≤ 2,607	≤ 4,794	200BLOOD8	200SBLOOD8
8	4 - 7	13 x 100	≤ 6,000	≤ 8,000	≤ 3,461	≤ 6,153		
8	8.5 - 10	16 x 100	≤ 6,000	≤ 8,000	≤ 3,461	≤ 6,153		
4	8	16 x 125	≤ 6,000	≤ 8,000	≤ 3,461	≤ 6,153		

Includes: (1) Centrifuge, (1) Built-in Angle Rotor, (8) Adapters 13 x 75 mm, (8) Adapters 13 x 100 mm

EBA 200 **PEDIATRIC TUBE** PACKAGE - 8

Tube Qty.	Volume (mL)	Size (mm)	200 RPM	200S RPM	200 RCF	200 S RCF	PKG. NO. (EBA 200)	PKG. NO. (EBA 200 S)
8	0.5	10.7 x 36	≤ 6,000	≤ 8,000	≤ 2,214	≤ 3,935	200BLOOD8-PED	200SBLOOD8-PED

Includes: (1) Centrifuge, (1) Built-in Angle Rotor, (8) Adapters 0.5 mL

EBA 200 **URINALYSIS** PACKAGE - 4

Tube Qty.	Volume (mL)	Size (mm)	RPM	RCF	PKG. NO.
4	12 KOVA	17 x 102	≤ 6,000	≤ 3,461	200URINALYSIS4
4	15 Conical	17 x 120	≤ 6,000	≤ 3,461	

Includes: (1) Centrifuge, (1) Built-in, Angle Rotor

EBA 200 **CUSTOM** PACKAGE

Supports over 19 application configurations, please inquire for more information

Tube types include: Standard, Blood, Pediatric, Urine, and Conical up to 15 mL

↓

hettweb.com/eba200

CONTACT YOUR LOCAL HETTICH REPRESENTATIVE TO LEARN MORE

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Hettich
LAB TECHNOLOGY

MEDCERT®
Certification Medical Only

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Andreas Hettich GmbH & Co. KG
Föhrenstraße 12
78532 Tuttlingen
Germany

has introduced, applies and maintains a Quality Management System in the area of:

Design, production, final inspection and distribution of

- **laboratory centrifuges**
- **centrifuges for separation of blood components for transfusion purposes**
- **incubators**
- **related accessories**
- **spare parts**

Respective service and support

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 09 June 2021

Report No.: 3654FS15F
Process No.: QS - 3654
Certificate No.: 3654GB445180803

Hamburg, 03 August 2018

MEDCERT Certification Body
(Markus Bianchi)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

MEDCERT®
Certification. Medical Only.

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Andreas Hettich GmbH & Co. KG
Föhrenstraße 12
78532 Tuttlingen
Germany

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Centrifuges for separation of blood components for transfusion purposes

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 09 June 2023

Report No.: 3654FS15F
Process No.: QS - 3654
Certificate No.: 3654GB410180803

Hamburg, 03 August 2018

MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Anexa 6.Analizator Hematologic automat 3Diff Emerald Cell Dyn

Parametrul Specificația
Tip sistem închis. Sistem inchis care utilizeaza doar 3 reactivi:diluent, liza, cleaner (reactivul de liza este fara cianuri)
Are posibilitate de inchidere programata si inchidere manuala;

- Cititor de cod de bare extern, in echipare standard
- Intretinere zilnica si saptaminala= ZERO
- mai putin de o interventie service/an

Metode de analiză- 3 diff. CD Emerald are la baza tehnologie impedanta electronica pentru diferentierea RBC si PLT si WBC numar total si spectrofotometrie.

Procedura de curățire- automată. Mentananta este automata. Întreținerea zilnică este procedură automată și întreținerea saptamanala automata. **Avantaj:** Procedurile de intretinere sunt memorate in soft-ul aparatului si pot fi printate pentru documentatia laboratorului.

Parametri determinați și calculați:
WBC RBC HGB HCT MCV MCH MCHC PLT LYM# MID# GRAN# LYM% MID% GRAN% RDW-SD RDW-CV PDW-SD PDW-CV MPV PCT
Capacitate (probe/oră)- **Procesare 60 probe/ora**
Diluarea- automată
Afișaj graphic. Da, monitor color cu touch screen
Imprimantă- încorporată. Aparatul este dotat cu imprimata matriceala sau inkjet cu buffer de memorie si port USB pentru imprimanta.
Sistem ID pacient da, posibilitate date demografice

- datalog numeric
- identificare alfanumerica a pacientului PID
- identificare alfanumerica a probei SID
- data/ora
- nume pacient
- hemoleucograma 3-part diff
- sistem de flag si alerta

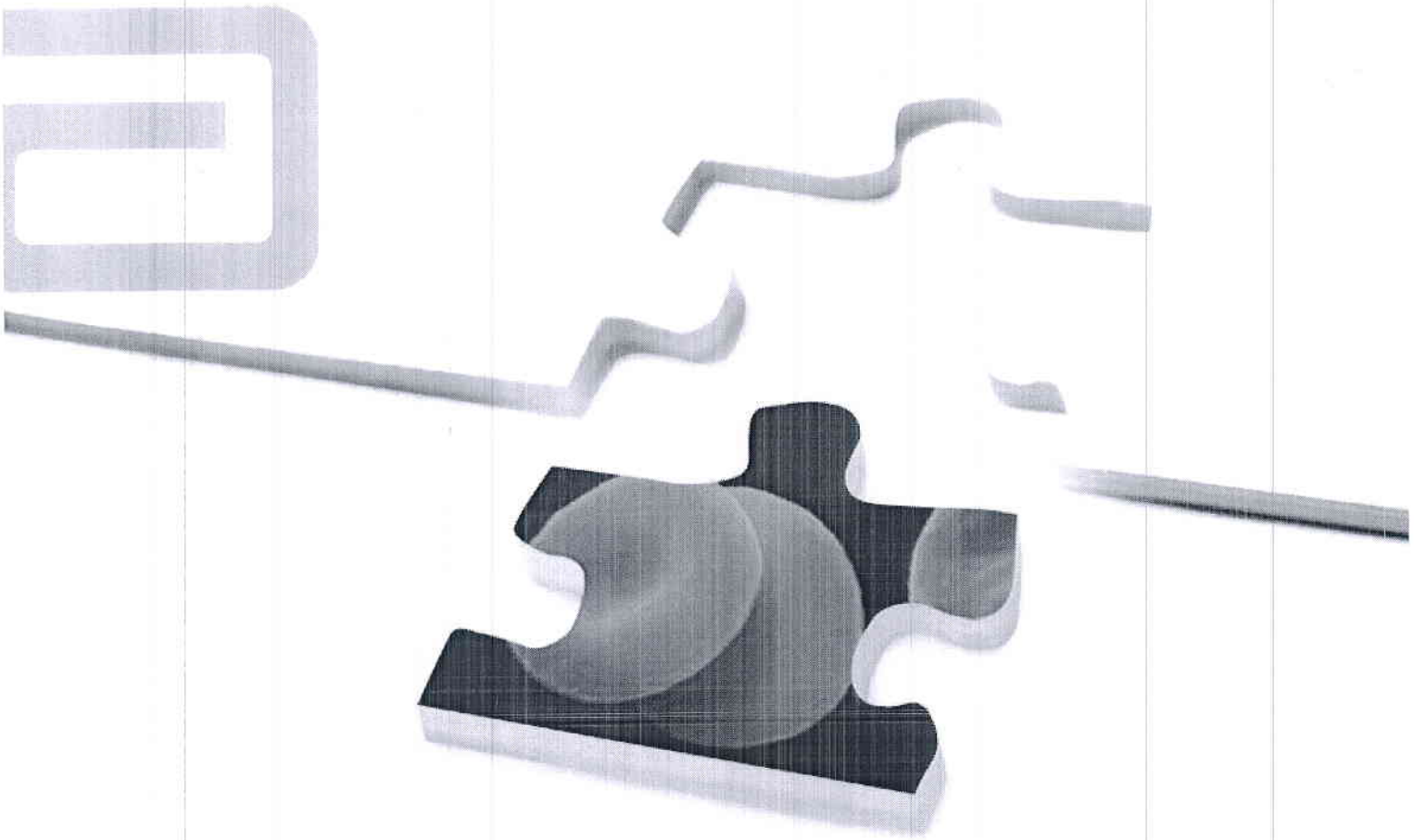
Introducerea datelor manual
Interfața PC da. Posibilitate de conectare la internet: (TCP/IP) si RS232.
Afișarea histogramelor- da
Stocarea datelor- da
Calibrarea- automată
Histograme: WBC- repartizarea leucocitelor după volum
RBC - repartizarea eritrocitelor după volum
PLT- repartizarea trombocitelor după volum
Afișarea pe ecran a tuturor datelor histograme rezultate grafice rezultate din arhivă date de service

- Afișarea rezultatelor pe imprimantă - Da -Aparatul are capacitatea de a accesa si printa datele in orice moment; Are posibilitate de printare automata si legare la o imprimanta externa
- Raportul tiparit (printat) cuprinde:

Limitele de referinta cu atentionari (flag) pentru valorile care depasesc limitele stabilite;

- Are trei sisteme de unitati de masura: USA (Standard) , Sistem de Unitati Internationale (SI), SI modificat- mod in mmol

Termenul de garantie 24 luni



Компактный. Мощный. Безупречно точный.

Высокая производительность при очень компактных размерах

- Надежные и точные результаты
- Внешний считыватель штрих-кода
- Русскоязычное меню
- Включение одной кнопкой
- Автоматическое выключение
- Бесшумный и легкий

Быстрый и простой в использовании

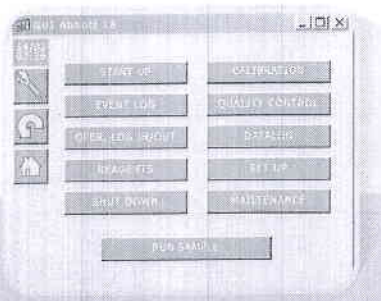
- Результат CBC менее, чем за 60 секунд
- Небольшой объем образца (9,8 мкл)
- Экономичный расход реагентов
- Нет ежедневного и еженедельного обслуживания

Put science on your side.

Abbott
A Promise for Life

CELL-DYN Emerald

Технические характеристики



Технологии и методы
- Электрический импедансный подсчет
- Абсорбционная спектрофотометрия
- Электронные клапаны
- Бесцианидные реагенты
- Цветной жидкокристаллический сенсорный экран
- RS-232 и TCP/IP LIS интерфейсы
- USB порты

Производительность
- До 60 образцов в час

Объем образца
- 9,8 мкл

Система управления данными
- Поиск по дате и порядковому номеру
- Расстановка флагов для границ нормальных значений
- Расстановка флагов для критических значений
- Хранение в памяти до 1500 результатов с гистограммами
- Сохранение до 60000 результатов на внешнем USB-носителе (флэшке)
- Программируемые границы нормальных значений
- Программируемые единицы измерения (для выхода на печать)
- Внешний считыватель штрих-кода (считывает code 128, code 39, Interleaved 2 of 5)

Система контроля качества
- 6 контрольных файлов
- 100 измерений в файле
- Графики Леви-Дженнингса
- Возможность загрузки контрольной информации с внешнего носителя
- Программа внешнего контроля качества в режиме on-line

Данные пациента
- Порядковый номер
- Буквенно-цифровая идентификация образца
- Буквенно-цифровая идентификация пациента
- Время и дата проведения анализа
- Имя пациента
- CBC с подсчетом 3-х популяции лейкоцитов
- Расстановка флагов и предупреждений

Предупреждение о разбросе данных
- Определяемые оператором границы верхнего и критического значений для пациента
- Определяемые системой границы аналитических измерений и регистрируемых значений
- Флаги о сомнительных результатах вследствие интерференции или патологии образца
- Флаги о сомнительных результатах, когда подсчет лейкоцитов свидетельствует о возможном наличии патологической популяции

Соответствие стандартам и требованиям безопасности
- UL61010A-1
- CE Mark (Европейское соответствие)
- CAN/CSA C22.2 No.1010.1-92
- ETL Mark (США)
- IEC 61000-3-2, 3-3, 4-2, 4-3, 4-4, 4-5, 4-6, 4-8, 4-11
- Harmonic emissions
- EN 55011 и EN 61000

Периферийные устройства
- Матричный или струйный принтер
- USB носитель (флэшка)
- Внешний считыватель штрих-кода

Габариты
- Высота 35 см
- Ширина 25 см
- Глубина 35 см
- Вес 9 кг (без учета реагентов)

Определяемые параметры

Лейкоциты	Эритроциты	Тромбоциты
WBC	RBC	PLT
LYM #	HGB	MPV
LYM %	HCT	PDW*
MID #	MCV	PCT*
MID %	MCH	
GRAN #	MCHC	
GRAN %	RDW	

* Клиническая значимость для этих величин не установлена и они не используются в лабораториях США.

Реагенты для CELL-DYN Emerald

Описание	Объем	Каталожный номер
Лизирующий реагент, бесцианидный (CN-Free Diff Lyse)	960 мл	09H47-02
Дилюент (Diluent)	10 л	09H48-02
Очищающий реагент (Cleaner)	960 мл	09H46-02

Контроли и калибраторы для CELL-DYN Emerald

Описание	Объем	Каталожный номер
Калибратор CELL-DYN 18 Plus Calibrator	2 x 2,5 мл	99110-01
Контроль CELL-DYN 18 Plus Control	12 x 2,5 мл	99109-01
Контроль CELL-DYN 18 Plus Control	6 x 2,5 мл	99105-01

ООО «Эбботт Лэбораториз»
Диагностическое отделение
141400, Россия, Московская область,
г. Химки, ул. Ленинградская,
владение 39, строение 5,
Тел.: (495) 258 42 70
Факс: (495) 258 42 71
www.abbottdiagnostics.com

AH2107/uk CELL-DYN Emerald Product Flyer 03/09/4

Abbott Hematology

Abbott

Declaration of Conformity

Certificate Identification: SC-09H39

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H39-01	35476	CELL-DYN Emerald Instrument	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 C2 Diagnostics, Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Rosemarie Lulu
Position:	Manager, Supplier Quality	Position:	Regulatory Affairs Project Manager
Date of Approval:	29 June 2016	Date of Approval:	28 June 2016
Date Issued:	JUN 29 2016	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 (Feb 26, 2015)	Effective (Date or Lot Number):	JUL 01 2016

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

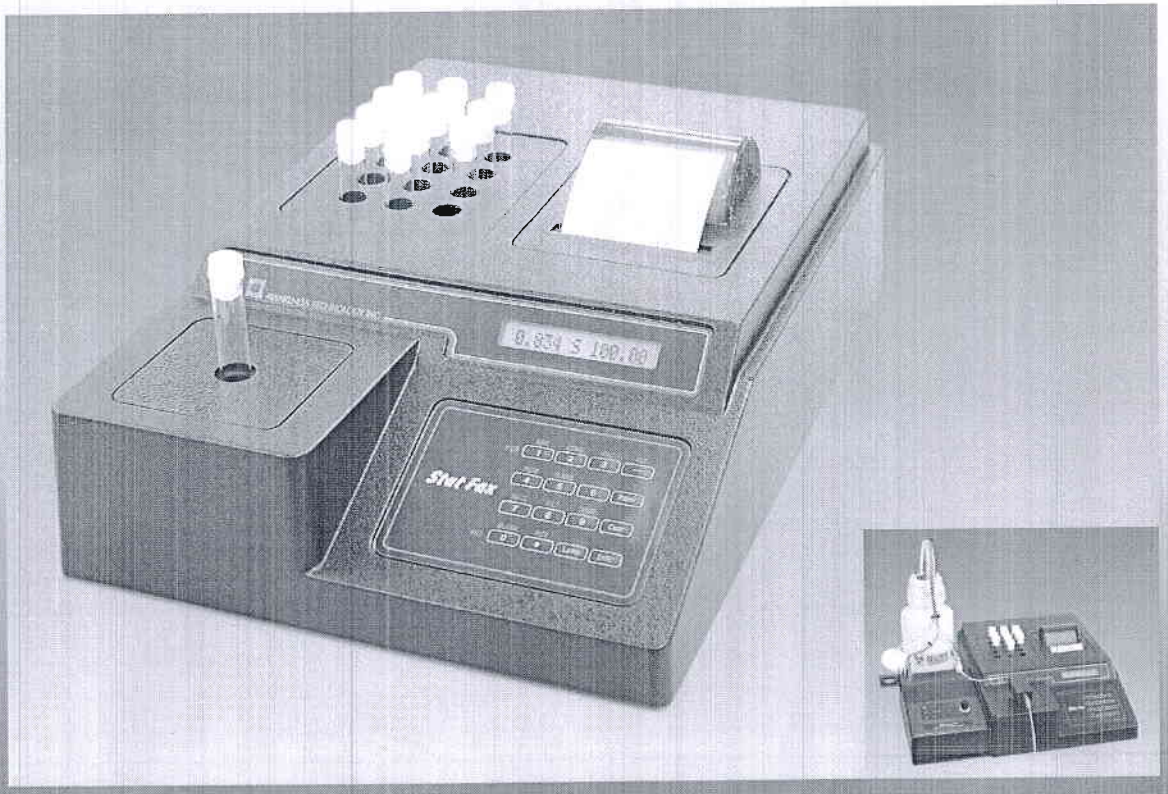
Abbott

Anexa 7.Analizator biohimic semi-automat Stat Fax 1904+

Domeniul liniarității de măsurare: Minim 0,00-3,00 unități de densitate optică (A)
Acuratețea fotometrului : +/- (1% din citire + 0,005 A)
Stabilitate Variația zero nu este mai mare de 0,005 A (timp de 8 ore)
Sursă de lumină: Tungsten lampă cu siguranțe
Lungimi de undă standard: 340, 405, 450, 505,545 si 630 nm;

Prelevarea de probe:
Volumul eprubetei:12mm
Volumul minim - tub (12 mm) 1 ml.
Volumul minim - Cuvetă 400gL.
Imprimanta integrate termica.
Afișaj ..... LCD
Tastatură 16 cheie, membrană cu buzunare.
Carcasa ignifuga și oțel.

Termenul de garantie 24 luni



Stat Fax® 1904Plus - Chemistry Analyzer

Inset - shown with Mosquito® Aspiration Flow Cell accessory

Features

- ⇨ Bichromatic optical system with six wavelengths including 340nm.
- ⇨ Pre-programmed calculations for both kinetic and endpoint assays.
- ⇨ Twelve-station 37°C incubation block and temperature-controlled read cell.
- ⇨ Easy to use with step-by-step prompting and built-in thermal printer with graphics capability.
- ⇨ Large, non-volatile memory to store more than 50 curves and test parameters.

Options & Accessories

- ⇨ Redi-Check® to monitor accuracy, linearity, and repeatability of Stat Fax® Chemistry Analyzer.

Mosquito® Aspiration Flow Cell

- ⇨ Powered from the Stat Fax® Chemistry Analyzer.
- ⇨ Keyboard selectable read volume from 250mL to 500 mL.
- ⇨ Software controlled with user prompts.
- ⇨ Internal extra-quiet vacuum pump.
- ⇨ All cables and connectors included.

Distributed by:

AWARENESS TECHNOLOGY, Inc. PO Box 1679, Palm City, FL 34991 (772) 283 6540 fax (772) 283 8020
web: http://www.awaretech.com email: info@awaretech.com

Cost Effective by Design®

Stat Fax® 1904 Chemistry Analyzer Specifications

Photometric

Linear Measurement Range:	0.0 to 2.5 Absorbance units (A).
Photometric Accuracy:	+/- (1% of the reading + 0.005A).
Stability:	Drift of no more than 0.005A in 8 hours/bichromatic.
Light Source:	Tungsten lamp with lamp saver feature.
Standard Wavelengths:	340, 405, 450, 505, 545 and 600nm. (alternate filters available from 340 to 700nm)
Filter Type:	IAD hardcoat interference, 10nm half bandpass.
Tube Size:	12 mm round is standard.
Minimum sample volume:	1mL for 12mm round tube, 250mL with Mosquito accessory.

Electronic

Display:	Alphanumeric, 16 character LCD.
Printer:	Thermal dot matrix, 20 characters per line, plus graphics.
Keyboard:	16-key, domed membrane switch, enunciating.
Power Requirements:	115V or 230V AC, 50-60Hz (switch selectable).

Software

Speed:	Reads, calculates and prints results - 3 seconds per tube.
Calculation Modes:	Single point calibration by standard or factor, multipoint calibration with point-to-point curve fit, rate by standard or factor (batch or singly).
Test Menu:	More than 60 open channels to store tests. Stores all parameters including wavelengths, calculations, unit codes, linear and normal ranges, rate timing, standard values, test names, and previous standard curve.

Other

Temperature	37°C, block stays on, cell has on/off switch.
Enclosure:	Painted flame-retardant ABS plastic cover with metal base.
Dimensions:	Approx. 9x13.5x5in. (24x34x13cm) weighs 10 lbs.(4.5kg).
Certifications:	NRTL listed, CE mark.

Mosquito® Aspiration Flow Cell specifications

Cell

Minimum aspiration volume:	250mL at 7"Hg vacuum.
Other Volume Options:	300, 350, 400, 450, 500mL.
Illuminated Volumes:	21mL.
Equivalent Pathlength:	1cm.
Cell Body:	Surgical grade stainless.
Windows:	1mm Pyrex.

Control Module

Power Input:	12V DC/0.7A from analyzer.
Valve:	Silicone pinch type.
Vacuum Sensor:	Piezoresistive bridge type.
Vacuum Regulation:	Better than 0.25" Hg.
Vacuum Pump:	Self contained.
Full Sensor:	Stainless conductivity probe.

Mosquito® is compatible with 1900 series chemistry analyzers with 12mm round read cell manufactured by Awareness Technology, Inc.

Doc. Stat Fax® Model - 1904/2400 S4V2 - 3/09

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Shipping and Service.

Certificate Number:
9362-7

Initial Certification Date:
March 28, 2012

Certificate Issue Date:
March 27, 2018

Certificate Expiry Date:
March 27, 2021

SCC Accredited CB-MS
OCSM Accrédité CCN

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

CE

Awareness Technology, Inc.

Declaration of Conformity

Product identification

Product name : Stat-Fax®, Chemistry Analyzer
Model/Type : P1904

Manufacturer

Name : Awareness Technology, Inc.
Address : PO Drawer 1679
Palm City, Florida
Country : USA

Representative:
Authorized Representative in Europe
Name : Emergo Europe
Address : Molenstraat 15
2513 BH The Hague
Country : The Netherlands
tel: +31 70 345 8570
fax: +31 70 346 7299

Means of Conformity

Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive:

98/79/EC

And is in conformance with the following standards:

EN 61326-1 / EN 55022
EN 61010-1

Signature

Place and Date: Awareness Technology, Inc. December 01,2003

Signature :

Name : Steve Andrus
Quality Manager

Chris Mauer
Compliance Engineer

Anexa 8. Reflecometru URYXXON ® Relax:

Caracteristici

- Benzi de testare: URYXXON ® Stick 10
- Capacitate: 50 teste/ h
- Memorie instrument de 200 rezultatele testelor de pacienți, inclusiv nume sau ID-ul pacientului
- Interfata Utilizator: ecran tactil, alfanumeric, protectie cu parolă
- Computer: Interfata USB pentru conectarea la PC-ul alternativ, interfata RS232 pentru conectarea la PC si PS / 2, interfata pentru conectarea tastaturii si / sau cititor de coduri de bare
- Cerinte de alimentare: 110-240 V AC,, automate de operare, alimentat cu baterie (opțional), cu 6 AA baterii
- Dimensiuni (AxLxI): 20x16x7.5 cm
- Greutate: 0.7 kg (fără baterii și alimentare)
- Operare: Interval de temperatură: 5-40°C, gama de umiditate: 20-80% umiditate relativă, fără condensare,
- Calibrare: automata, auto-calibrare
- Termenul de garantie 24 luni

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Discription see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-08-21
Certificate Registration No.:	SX 60129407 0001
An audit was performed. Report No.:	21265422 003
This Certificate is valid until:	2020-05-28

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-08-21

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel. +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 60129407 0001
Report No.: 21265422 003

Organization: Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Scope: Design and development, production and distribution of medical test strips and reflectometers for evaluation and products for bioanalytical sample preparation.

Sites included:

- Valencienner Str. 11
  52355 Düren, Germany

Activities: Distribution, warehousing, manufacturing and quality control of reflectometers, customer service

- Bahnstr. 120
  52355 Düren, Deutschland

Activities: Storage of raw materials and intermediate products

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-08-21

Dipl.-Ing. Sven Hoffmann

EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following reflectometer for professional use

Name of product:	URYXXON® Relax
Reference number:	930 88
Type:	URINE MULTI-CONSTITUENT TEST STRIPS EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 27.08.2014

i.A. Markus Meusel (QAM, Reg. Affairs)

URYXXON® Relax

URYXXON® Relax – automated urine analysis at the point of care

The URYXXON® Relax provides dependable urine status results to detect early stages of many diseases such as diabetes, kidney disease and urinary tract infections. Instrument-read results have long proven to be advantageous for both, busy health care professionals and patients. URYXXON®Relax readings eliminate the subjectivity of visual colour interpretation. The comprehensive interface options and the optimized printouts minimize risks associated with manual transcriptions. Reliable results can be obtained virtually immediate at the point of care.

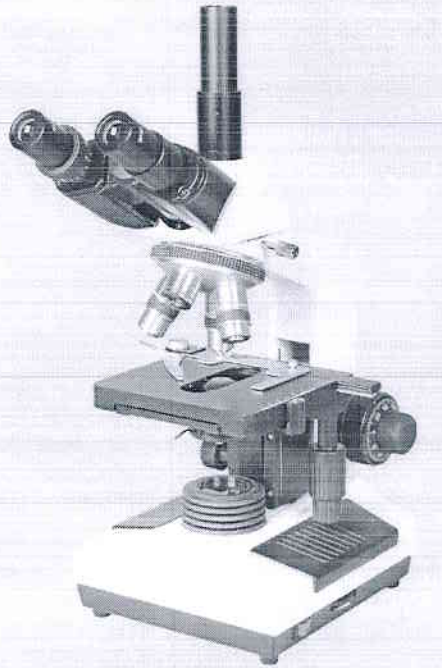
The URYXXON® Relax makes urine analysis simpler and more reliable.

Technical data and ordering information

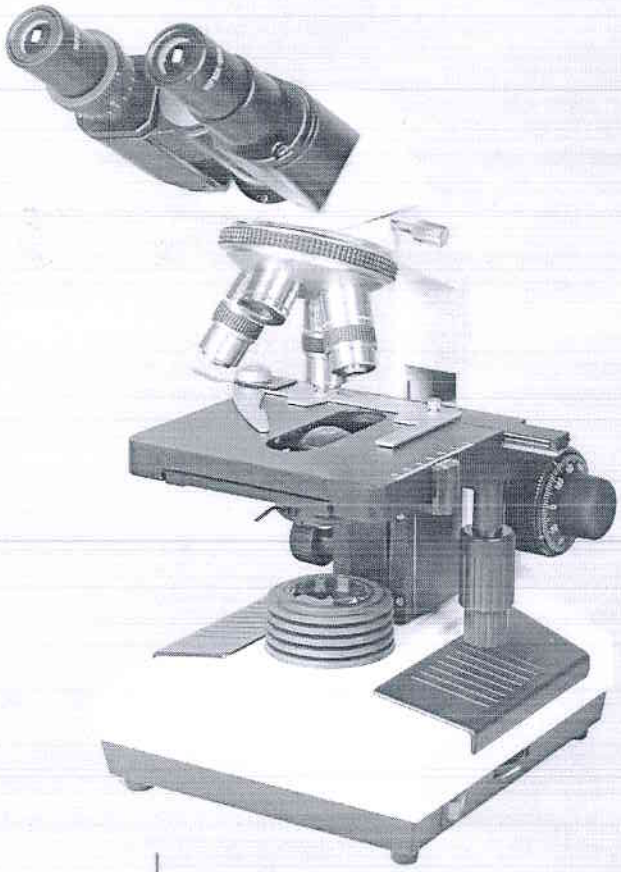
Test strips	URYXXON®Stick 10
Capacity	50 strips/h
Instrument memory	200 patient test results including name or patient ID
Interface	User: Touch screen display, alphanumeric input, password protection, Computer: USB interface for connection to PC alternatively RS232 interface for connection to PC and PS/2 interface for connection of keyboard and/or barcode reader
Power requirements	110-240 V AC, automatic, Battery powered operation (optional) with 6 AA batteries
Dimensions	Depth: 20 cm (8 inches) Width: 16 cm (6 inches) Height: 7.5 cm (3 inches)
Weight	Weight: 710 g (1.90 lb) (without batteries and power supply)
Operation	Temperature range: 5-40 °C (41 °F-104 °F), Humidity range: 20-80% relative humidity, noncondensing, Calibration: automatic, self-calibrating
Reference	93088

Anexa 9 Microscop biologic, XSZ-PW207

Vizualizarea capului: Microscop biologic cu cap binocular seidentopf, interval de reglare a distanței interpupiliare 48-75mm, rotire 360 ° a tubului ocular cu înclinare la 30 °
Ocular: WF10X;
Revolver- pentru 4 obiective, Click-stop;
Obiective: Obiective Plan Achromat: 4x, 10x, 40x, 100x/Ulei,
Treapta :miscare mecanica dubla: 140mmX132mm/75mmX45mm
Focusare:Ajustare coaxial aspra si fina , Distanta de focusare 30mm , Interval de focusare 0.002mm
Condensator: Abbe Brightfield cu diafragma 1,25, cu diafragmă iris și filtru.
Iluminație: Lampă cu halogen 6V / 20W sau LED 3W, luminozitatea reglabilă
Accesorii standarte: Lampa 6V/20W-1 buc; filtru albastru -1 buc,ulei de imersie -1 buc;
Accesorii optionale: cap trinocular; set contrast de faza (10x, 20x, 40x, 100x); Condensator de câmp închis (uscat sau ulei);



XSZ-PW207T



XSZ-PW207

Specification

Viewing Head	Biological microscope with seidentopf binocular head,Interpupilary distance adjustment range 48~75mm,360° rotation of eyepiece tube with inclined at 30°	
Eyepiece	WF10X	
Nosepiece	Quadruple,Click-stop	
Objective	Achromatic objective: 4x, 10x, 40x(s), 100x(s,oil)	
Stage	Double layers mechnical stage, 140mmX132mm/75mmX45mm	
Focusing	Coaxial coarse and fine adjustment, Focusing range 30mm,Focusing interval 0.002mm	
Condenser	Abbe NA=1.25 with iris diaphrame and filter	
Illumination	6V/20W halogen lamp, or 3W LED, adjustable brightness	
Standard Accessory	* 6V/20W spare halogen lamp	* BGX1-20(1A) fuse
	* Blue filter	* Immersion oil
	* Dust cover	* Instruction manual in English
Optional Accessory	Trinocular head	
	Phase contrast kit (10x, 20x, 40x, 100x)	
	Dark field condenser (dry or oil)	

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00118Q32812R0S/3302

We hereby certify that

Ningbo ProWay Optics & Electronics Co.,Ltd.

Unified Social Credit Code: 9133021257367706XW

No.301 Jingu Middle Road (west), Yinzhou District, Ningbo City, Zhejiang Province, China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Production and Service After Sales of Microscopes

Certified since: March 29, 2018 Valid from: March 29, 2018 Valid until: March 28, 2021

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C001-M

Signed by: Wang Kejiao

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

Q 0091034

2015年版

C E R T I F I C A T E

TÜVRheinland®

of Conformity
Low Voltage Directive 2014/35/EU

Registration No.: **AN 50347784 0001**

Report No.: **14706948 002**

Holder: Ningbo ProWay Optics & Electronics Co., Ltd.
No.301 Jingu Middle Road(west),
Yinzhou Investment & Business
of Ningbo
315104
P.R. China

Product: Microscope
(Biological Microscope)

Identification:

XSZ-PW106	XSZ-PW107	XSZ-PW108	XSZ-PW109
XSZ-PW206	XSZ-PW207	XSZ-PW208	PW-BK2000
PW-BK5000	PW-BK5000FT	PW-BK5000LCD	N-PW300
(Pro.Way)			

Serial No.: n.a.
Remark: Refer to test report 14706948 001-002 for details.

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with Annex I of Council Directive 2014/35/EU, referred to as the Low Voltage Directive. This certificate does not imply assessment of the series-production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to Annex IV of the Directive.

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Jianzhong Mao

Date 15.06.2016

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE