

Anexa 1 Pat multifunctional pentru adulti Model:MYS-5400NS


Pat multifunctional pentru adulti			
Paturi electrice complet motorizate pentru sectii de profil general si paturi electrice pentru sectii de reanimare			
Descriere			
Parametrul		Specificatia Solicitata	Specificatia Ofertata
Tip		Multifunctional cu 5-6 pozitii	Multifunctional cu 5-6 pozitii
Tip pacient		adult	adult
Controlul pacientului	tip	Toate butoanele sa fie insotite de simboluri grafice	Toate butoanele sunt insotite de simboluri
	Functionalitati	pozitionare sedentara	pozitionare sedentara
		pozitionare trendelenburg	pozitionare trendelenburg
		pozitionare anti-trendelenburg	pozitionare anti-trendelenburg
Controlul de catre asistenta	Blocarea control pacient	da	da
Greutatea maxima a pacientului	Cadru pentru eticheta pe spatiu	>220 kg	250kg
Tnaltime	Ajustabila	> 74 cm	Da intre 46-74 cm
	Diametru	>12.5 cm	Ø12.5 cm
Rotile			
	Sistem de blocare	la minim 2 rotile	Da , sistem central de frinare (toate 4 rotii)
Parapete de protectie laterale		da	da
Reglare manuala a partilor importante In caz de lipsa de energie electrica		da	da
Alimentare		220 V, 50 Hz	220 V, 50 Hz
Saltea		ortopedica	inclusa

Anexa 2 Pat multifunctional pentru adulti (5-6 pozitii) Model:MYS-5400NS+ 28566 Gima

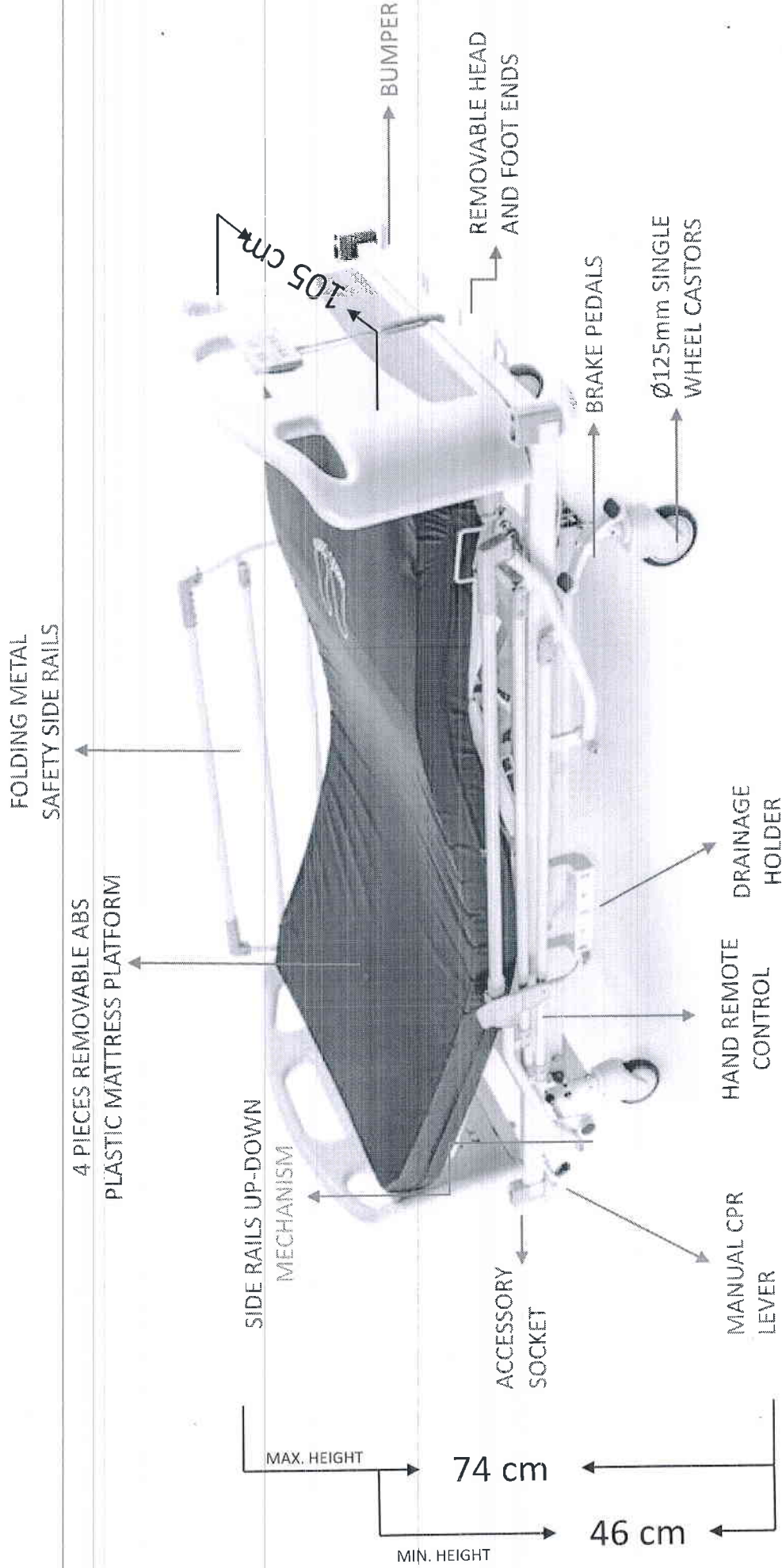
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	Sistem de blocare	la minim 2 rotile	Da , sistem central de frinare (toate 4 rotii)
Parapete de protectie laterale		da	da
Reglare manuala a partilor importante In caz de lipsa de energie electrica		da	da
Alimentare		220 V, 50 Hz	220 V, 50 Hz
Saltea	ortopedica	inclusa	inclusa
	Antidecubit+accesorii	da	Da, 28566 Gima

MYS-5400NS HOSPITAL BED WITH 4 MOTORS

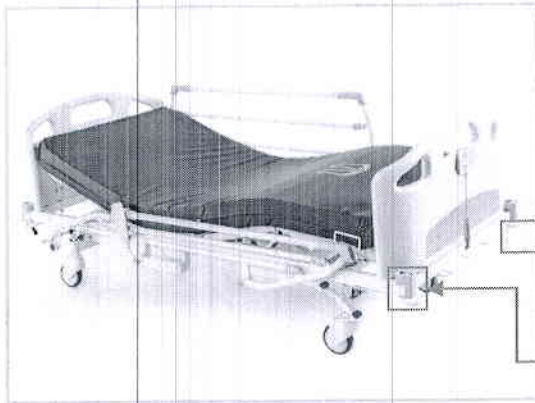


Meyosis®

TECHNICAL INFORMATION



PATIENT MANAGEMENT SOLUTIONS



BUMPERS

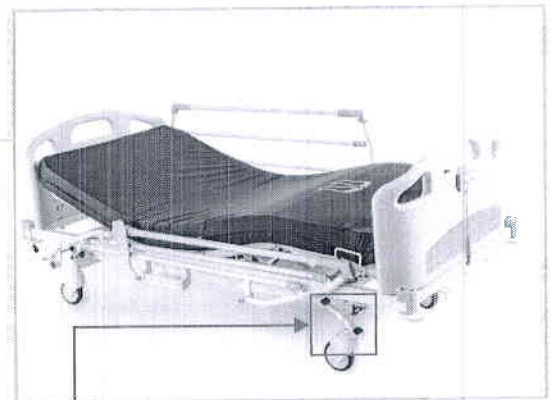
- Bumpers are located at each corner of the bed to protect the bed against crushes.

ACCESSORY SOCKETS

- Accessory sockets at each corner of the bed for IV poles and traction sets.
- One adjustable IV pole is provided with the bed.

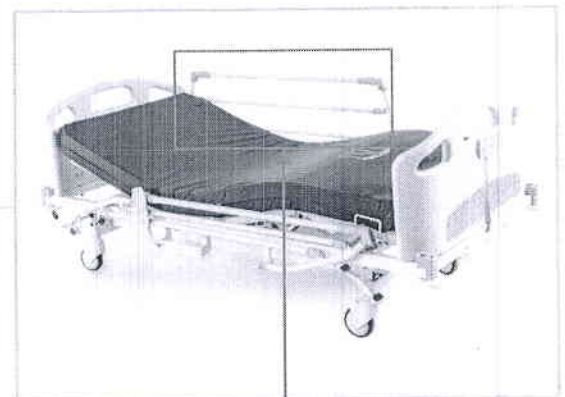
BRAKE AND STEER SYSTEM

- Ø125 mm wheels with linked (central) braking and steering system.
- Steer castor helps to keep the bed on a straight line in the direction of travel. Twin wheels are optional.



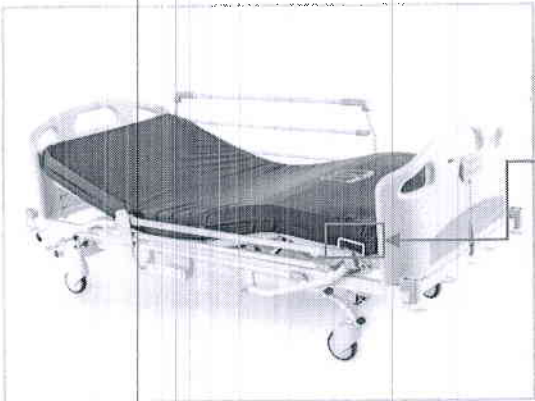
FOLDING METAL SAFETY SIDE RAILS

- Foldable metal side rails painted with electrostatic epoxy polyester.
- Ergonomic, robust and easy to use.

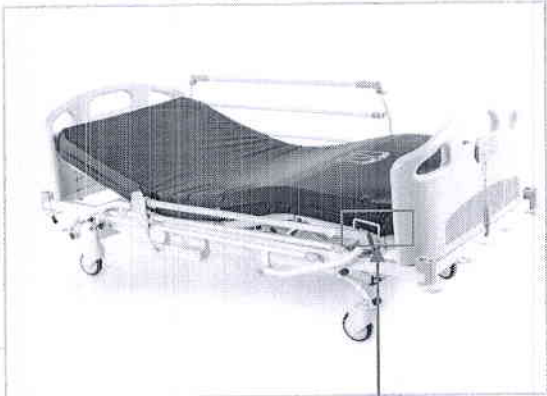


PATIENT MANAGEMENT SOLUTIONS

RATCHET CALF SECTION ADJUSTMENT



- Calf section adjustment is ratchet assisted.
- Ratchet has ten levels .



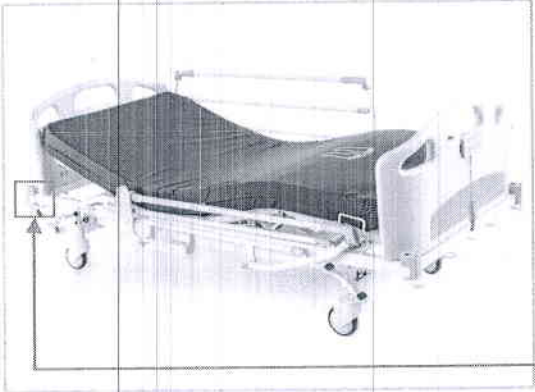
DRAINAGE BAG RAILS

- Dual-sided integral drainage bag rails with three hooks.



MANUAL CPR

- Manual CPR lever is gas spring assisted.



PATIENT MANAGEMENT SOLUTIONS



HAND REMOTE CONTROL

- Height, backrest, legrest (knee), positions can be adjusted by Hand Remote Control

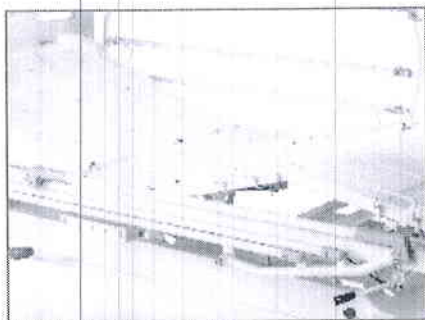


NURSE REMOTE CONTROL

- Height, backrest, legrest (knee), trendelenburg, reverse trendelenburg and auto CPR positions can be adjusted by Nurse Remote Control.

REMOVABLE HEAD AND FOOT ENDS

- Head and foot ends are removable and easily mountable.

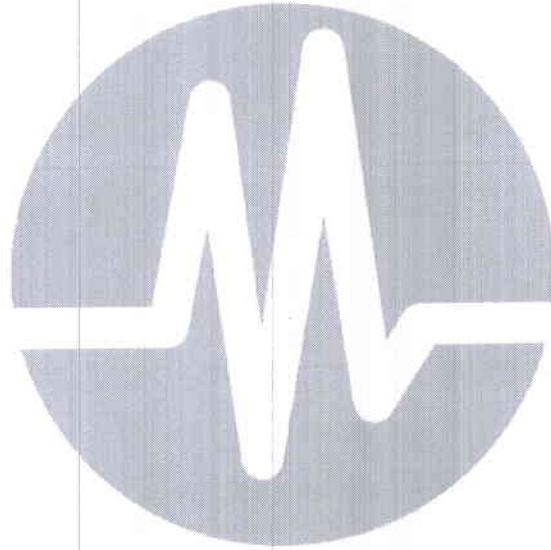


4 PIECES REMOVABLE ABS PLASTIC MATTRESS PLATFORM

- Robust, cleanable and ergonomic

OTHER SPECIFICATIONS:

- Safe working load of the bed is 250 kg.
- Multiple colour options
- Oxygen cylinder holder



MEYOSİS HASTANE EKİPMANLARI SAN. VE TİC. A. Ő.

Headquarters: Küçükbakkalköy Mh. Kayışdağı Cd N:137/1 Çelik
Plaza, Kat:4 Ataşehir – İstanbul

T:+902165746738 F:+902165746739

Manufacturing: Devekaldırımı Caddesi No :10 Bağcılar –
İstanbul

www.meyosis.com



GIMA

BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)

Code: 28566
Category: Intensive care anti-decubitus mattresses
Unit of sale: 1 kit
Minimum order: 1
Type: Medical device
Class: I
NSIS: 817830
CND: Y033399
EAN13: 8023279285666



Description:

• **BUBBLE MATTRESS**

Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side. Cold-resistant -30 degrees.

Flaps length: 50+50 cm (top + bottom).

• **PUMP SYSTEM**

Special silent pump for an excellent pressure regulation by a knob on the front panel. It can be hung to any kind of hospital bed frame by means of two adjustable hooks. For use with bubble or alternating cell mattresses.

Technical Specifications:

Bubble mattress:

- Total size: 200 x 90 x 7 cm
- Cell height: 7 cm (2.7")
- Material: PVC
- Thickness: 0.32 mm
- Number of cells: 130
- Suitable for persons up to: 135 kg

Pump system:

- Size: 25 x 12 x h 10 cm
- Operating voltage: 220 V, 50 Hz
- Working pressure: 40-100 mmHg
- Air output: 6-7 liter/min
- Cycle time: 6 min
- Plastic casing: Taiwan chimei ABS
- TUV-CE IEC/EN60601-1; 60601-1-2



Certificate

ISO 13485 : 2016

MEYOSİS HASTANE EKİPMANLARI SAN. VE TİC. A.Ş.

Center: Kayışdağı Cd. Çelik Plaza No: 137-1 Kat: 4 Ataşehir/İstanbul/TURKEY
Production: Devekaldırımı Cd. No :10 Mahmutbey Bağcılar
/İstanbul/TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

SCOPE

Production, sale and marketing of patient cots and mechanical, hydraulic, electric, motor, electromechanic, equipped patient cages, technical service

GROUP CODE

M11

Certificate No	TC-75127
Registration Date	06.05.2019
Reissue Date	
Expiry Date	05.05.2020
Certificate Period	3 Years (Form the date of registration)
Exclusion	7.5.5/7.5.7/7.5.9.2



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kat:1 / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com





Certificate

ISO 9001 : 2015

MEYOSİS HASTANE EKİPMANLARI SAN. VE TİC. A.Ş.

Center: Kayışdağı Cd. Çelik Plaza No: 137-1 Kat: 4 Ataşehir/İstanbul/TURKEY
Production: Devekaldirımı Cd. No :10 Mahmutbey Bağcılar /İstanbul/TURKEY

This certificate shows that the quality management system of the above company was approved by PCA certificate for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

Production, sale and marketing of patient cots and mechanical, hydraulic, electric, motor, electromechanic, equipped patient cages, technical service

EA CODE

23

Certificate No : KY-26514
Registration Date : 06.05.2019
Reissue Date :
Expiry Date : 05.05.2020
Certificate Period : 3 Years (From the date of registration)
Exclusion :





PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Ataturk Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com

FR.86 Rev.4



DICHIARAZIONE DI CONFORMITA' / DECLARATION OF CONFORMITY

La Società GIMA S.p.A., con sede a Gessate (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:

We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / Medical Devices	Codici/Ref. #
MATERASSO A BOLLE + COMPRESSORE (28564+28565) BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)	28566

classe di rischio I non sterile, in accordo all' Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:

risk class I non sterile, according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all' Allegato VII della sopra citata direttiva.
are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

GIMA S.p.A.

Direttore Generale
Dr. Giulio Manzoni



GIMA S.p.A.

Responsabile Direzione
Nicola Manzoni

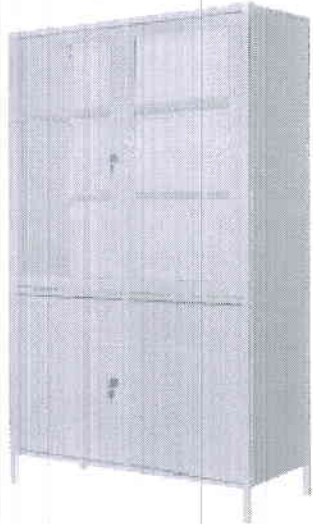


Gessate, 10/11/2016

Anexa 3 Dulap pentru medicamente, SM-2C, Zavet

Specificatie tehnica solicitata	Specificatie tehnica oferita
<p>Dulap medical de metal jumătate de închidere, cu 4 uși închise cu cheie, vopsit cu vopsea alba, rezistentă pentru toate soluțiile de dizinfecție.</p> <p>Partea de sus a dulapului 3 rafturi din oțel inoxidabil.</p> <p>Partea de jos a dulapului 2 rafturi din oțel inoxidabil.</p> <p>Picioarele în cauciuc.</p> <p>Dimensiuni orientative: 1680 mm (h)*800 mm*320mm</p>	<p>Dulap medical de metal jumătate de închidere, cu 4 uși închise cu cheie, vopsit cu vopsea alba, rezistentă pentru toate soluțiile de dizinfecție.</p> <p>Partea de sus a dulapului 2 rafturi din oțel.</p> <p>Partea de jos a dulapului 1 raft din oțel.</p> <p>Picioarele în cauciuc.</p> <p>Dimensiuni orientative: 1610 mm (h)*955 mm*400mm</p>

Dulap pentru medicamente SM-2C



Шкаф медицинский двустворчатый с сейфом ШМ-2С предназначен для размещения инструментов, материалов и медикаментов в перевязочных, операционных и других лечебных учреждениях. Каркас шкафа двустворчатый изготовлен из металлического профиля и окрашен белой порошковой краской. Нижняя часть выполнена цельнометаллической и запирается на ключ. Внутри сейфа имеется металлическая полка, максимально допустимая нагрузка 30 кг. В верхней части шкафа задняя и боковые стенки металлические, передняя дверь стеклянная. По желанию заказчика шкаф может быть цельнометаллическим. Шкаф имеет две металлические полки. Кромки на дверях и передние кромки на полках обработаны во избежание порезов. Верхняя дверь фиксируется за счет магнита. Конструкция шкафа не имеет выступающих и острых частей, что обеспечивает предупреждение травм при эксплуатации. Шкаф по конструкции разборной, поставляется потребителю в разобранном состоянии. Габаритные размеры ШМ-2С (гл*шир*выс): 400*955*1610 мм.

SZUTEST

CERTIFICATE

SZUTEST UYGUNLUK DEĞERLENDİRME ANONİM ŞİRKETİ

Hereby declares on the basis of the positive results of the certification audit that the medical-devices quality management system implemented by;

"Zavet Company" Subsidiary

Pivnichno- Syretska St, 3, Kyiv, Ukraine

Was found to be in compliance with the requirements of

ISO 13485:2003

The present certificate is valid for the following products and processes

**Design, Manufacturing, Sales and Service of
Medical Stretchers, Medical Beds, Medical Chairs & Eye Charts**

Registration No : 31701101
Issue Date : 11.01.2017
Expiration Date : 10.01.2020

This certificate is valid if company meets the certification requirements of SZUTEST.

**Deputy General Manager
Rukiye BALKAN**



FR.MED.01 R:00



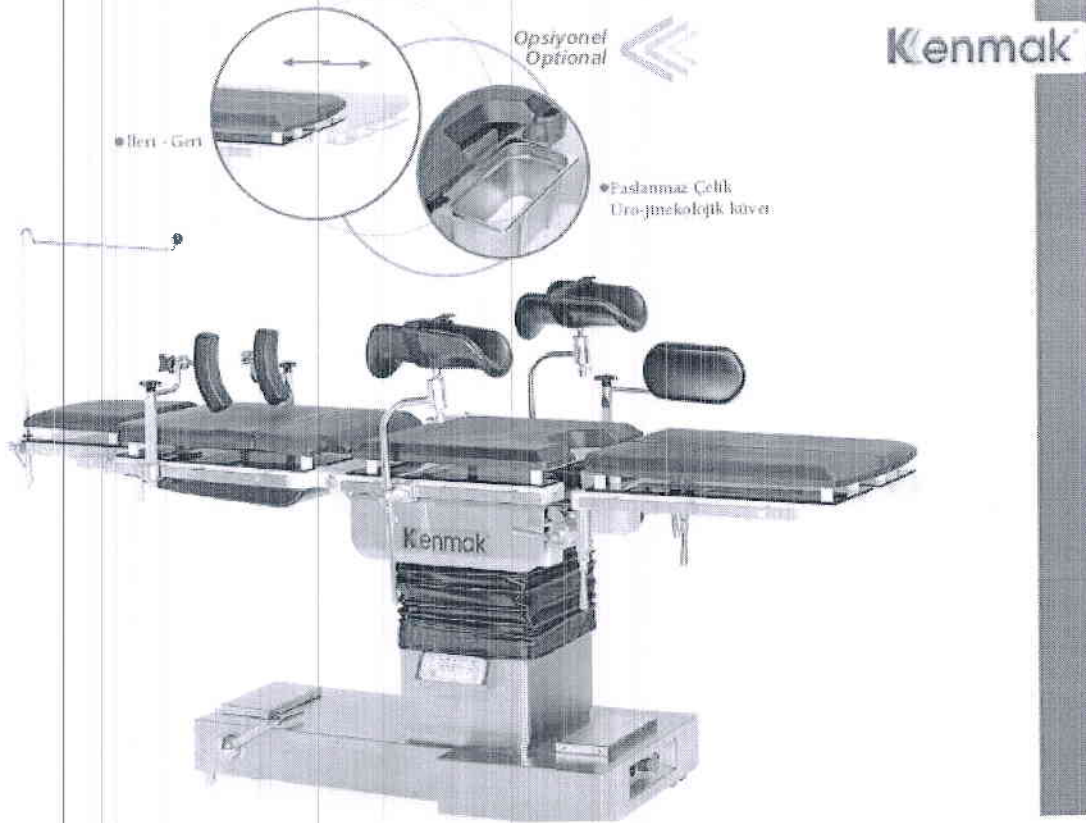
SZUTEST Uygunluk Değerlendirme A.Ş.
Szutest Plaza, Nato Yolu Cd. Çam Sk. No:7
Ümraniye 34775 İSTANBUL / TÜRKİYE

T: +90 216 469 46 66
F: +90 216 469 46 67

444 9 511
Szutest.com.tr

Specificație Completată		
Dispozitivul Medical		Masă pentru operații cu 5 secții
Modelul		K019/OPTA-20
Cantitatea		1 Bucăți
Țara de origine		Turcia
Producătorul		Kenmak
Masă pentru operații cu 6 secții		
Parametrul	Specificația	Specificație propusă
Descriere	Masa de operații oferă o suprafață corespunzătoare care susține corpul pacientului în timpul procedurilor chirurgicale, stabilizarea poziției pacientului și furnizarea câmpului chirurgical de expunere optimă.	DA
Poziționarea mesei	Reglarea înălțimii-limita de jos	75- 95 cm
	Trendelenburg	≥25 grade
	Inversa trendelenburgului	≥25 grade
Secțiile mesei	5 secții	6 secții
Înclinarea:	Inclinare Laterală	≥20 grade
	Sectia din spate	de la +80 la -40 grade
	Sectia de la talpa/picior	de la +20 la -90 grade
	Sectia de la talpa/picior	detasabila
	Sectia de la talpa/picior	divizata
	Sectia cap	de la +45 la -45 grade
Greutatea pacientului	≥ 200 kg	da
Radiotranspatenta	da	da
Utilizarea radiologica sau fluoroscopie	Tunel pentru casete X-ray	pe toată lungimea mesei
	Accesibilitatea brațului C	da
	Mărimea casetelor	minim 35x43 cm
Atașarea de bază	mobilă	da
Roti	da	da
sistem de frinare a bazei	da	da
Alimentarea	220 V, 50 Hz	da
Telecomanda	da	da
Șine laterale pentru accesorii	pe toată lungimea mesei	da
pupitru de comanda	da	da
Actiune electromecanica	da	da
Accesorii	suport cot	2 unit.
	suport umăr	2 unit.
	suport picioare	2 unit.
	suport torace	2 unit.
	suport mână (decubit lateral)	1 unit.
	stand pentru perfuzie	1 unit.
	curea pentru fixarea corpului	1 unit.
	suport pentru ecran anestezie	1 unit.

OPERATING TABLE TECHNICAL SPECIFICATIONS (K019/OPTA-20)

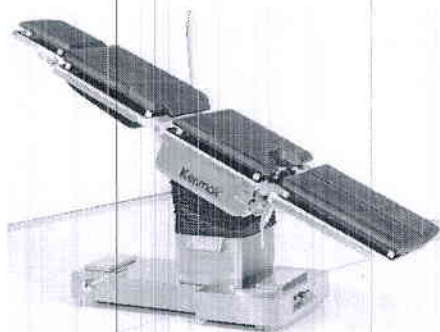


1. The table is designed suitable to be used for general surgery, orthopedic, eye surgery, neurology, HNT and for other different operations.
2. Table top is made up of minimum four sections including; head section, back section, seat section and footplate section with left and right parts.
3. Main body materials and all parts of the accessories is manufactured from stainless steel.
4. Stabilization tolerance of the table is in a structure not risk the patient during operation. This tolerance rates should not exceed motor spaces of the motors operating electro mechanical system.
5. On the table top, there has a mattress, with 5cm, durable to fluid and made up of anti static seamless polyurethane or viscous elastic). Mattress shall be taken off when needed.
6. Table top is x-ray radiolucent to permit radiological examinations. In order to perform radiological diagnosis; there has places for x-ray film cassettes to be placed under metal chassis of the table. On the other hand, table top has longitudinal sliding movement (minimum 20 cm) suitable to use C -Arm x-ray.

7. On the seat section of the operating table, there has span for perinea approach.
8. Table base is appropriate for easy use of C-arm x-ray device.
9. Dimensions of the table, except for accessory rails, is as written below in approximately:
 - Width : 55 cm.
 - Length : Minimum 202 cm.
 - Height : Minimum 78 cm, Maximum 108 cm (with mattress).
10. Operating table has an electro- mechanic motor system. Movements of the operating table including height, back section, trendelenburg / reverse trendelenburg and lateral tilt is controlled by means of remote hand controller commanding electro-mechanic system.
11. By hand command set with microprocessor, at least three different position of the table is memorized, Flex and Re-Flex movements is made by single button and it is stayed at required angle. No matter at what position the table is, it shall go to minimum level and make itself flat position by reset button.
12. There has buttons showing reset, trendelenburg, reverse trendelenburg, lowering, rising, lateral tilt (right and left) and sliding movements.
13. Back section of the operating table is moved minimum 70 degrees up and 30 degrees down by means of hand controller and controller on the table column.
14. The table has Flex and Re-Flex movements.
15. Back section of the table has an angle of 215 degrees as convex and 115 degrees as concave for kidney operation position.
16. Operating table should make minimum 30 degrees of trendelenburg and minimum 30 degrees of reverse trendelenburg movement by means of hand controller and controller on the table column.
17. Lateral tilt movement of the operating table is arranged minimum 25 degrees right and minimum 25 degrees left by means of hand controller and controller on the table column.
18. Head section of the operating table is arranged mechanically and shall be removed completely from the table.
19. Leg sections of the operating table is arranged mechanically and shall be removed completely from the table.
20. Left and right parts of the leg section of the table is moved independently at horizontal and longitudinal platforms.
21. Each sub parts of the leg section of the table which consist of two parts is moved mechanically minimum 35 degrees up and minimum 90 degrees down and is fixed at desired point. Each foot section is opened minimum 180 degrees from each other at horizontal platform.
22. At the two sides of back, seat and leg sections of the operating table there has accessory rails that made up of stainless steel. Accessory clamps is made up of chromium materials.

23. Operating table should operate with 220 Volt, 50-60 Hz City electricity current. Additionally, operating table has automatically charged battery system not needing electricity. It shall perform 25 full movements by battery.
24. Emergency stop button of the table is on the table base and when pushed to this button, all electrical circuit is cut and when re pushed to this button, system is active and memorial adjustments y of the table is kept the same.
25. There has a back up control panel placed on column of the table to be used for performing all main functions of the table that performed by hand controller and can be used on the body to operate the functions, when hand controller is not functional. This back up control panel should enter into service automatically when hand controller is out of service.
26. The table has wheels and is fixed at required position by means of electrical hand controller or foot pedal.
27. Operating table is delivered together with the accessories written below

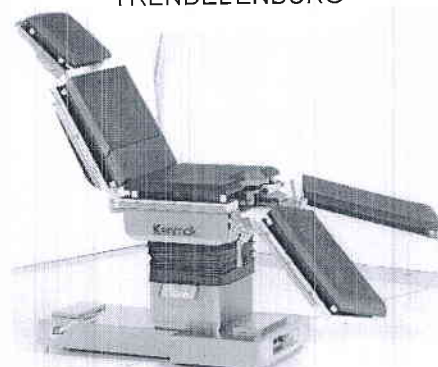
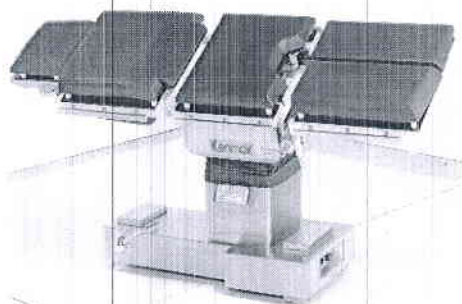
- | | |
|--------------------------------------|----------|
| • Narcosis frame with clamp /adaptor | 1 Piece |
| • Serum holder with clamp /adaptor | 1 Piece |
| • Hand (Arm) support | 1 Pieces |
| • Body restraining strap | 1 Piece |
| • Hand wrist strap | 1 Pieces |
| • Gynecological leg support | 2 Pieces |
| • Shoulder support | 1 Pieces |
| • Lateral support | 1 Piece |



TRENDELENBURG

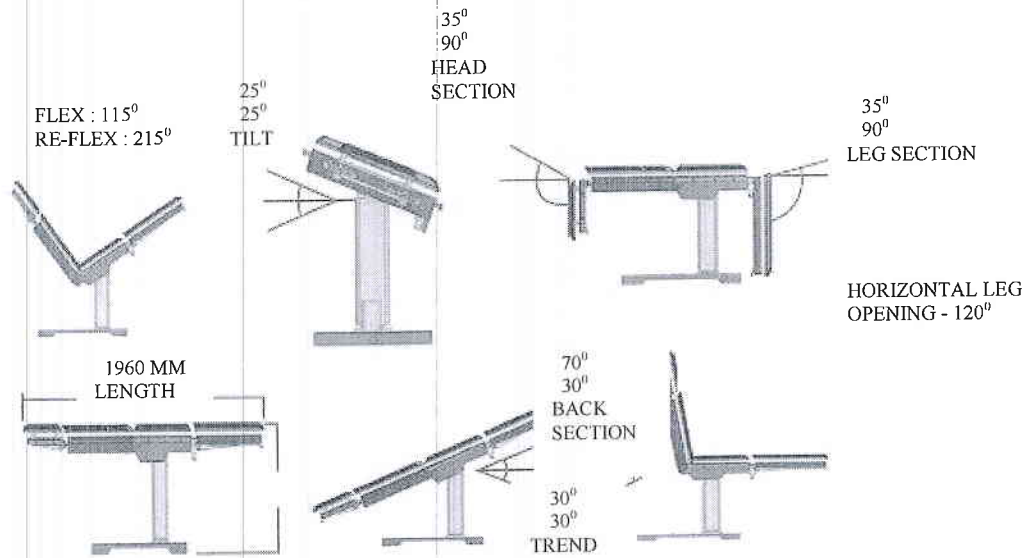


REVERSE
TRENDELENBURG



BACK /LEG/HEAD SECTION
POSITIONS

RIGHT/LEFT TILT



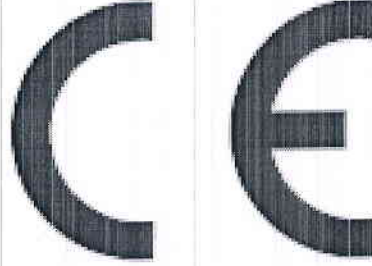
STANDARD ACCESSORIES

- Narcosis frame with clamp/adaptor 1 piece
- Serum holder with clamp/adaptor 1 piece
- Hand(Arm) Support 1 pieces
- Body Restraining strap 1 piece
- Hand wrist strap 1 piece
- Gynecological leg support 2 pieces
- Shoulder support 2 pieces
- Lateral support 1 piece

OPTIONAL ACCESSORIES

- X-RAY CASSETTE HOLDER
- IRRIGATION CUP
- SILIKONE HEAD PED
- KIDNEY ELEVATORVAT
- SILIKONE ARM PED
- WRISTLET STRAP
- 200 MM LONGITUDINAL SLIDING MOVEMENT

Kenmak®



EC DECLARATION OF CONFIRMITY AT UYGUNLUK BEYANI

We, **KENMAK Hastane Malzemeleri ve Elektrostatik Boya San. Tic. ve A.Ş.**, hereby declare that the below mentioned products have been designed and manufactured according to Directives of European Commission and related other standarts.

RULE 1 CLASS 1- 93/42/EEC ANNEX-7
TS EN ISO 13485
TS EN 60601
TS EN ISO 14971
TS 9215

Biz, KENMAK Hastane Malzemeleri Ve Elektrostatik Boya San. Tic. ve A.Ş., ekte verilen ürünleri Avrupa Komisyonu direktifi ve ilgili diğer standartlara uygun olarak tasarladığımızı ve ürettiğimizi beyan ederiz.

KURAL 1 SINIF 1- 93/42/EEC EK-7
TS EN ISO 13485
TS EN 60601
TS EN ISO 14971
TS 9215

Date of Beginning / Başlangıç Tarihi : 16.01.2018
Expiry Date / Bitiş Tarihi : 16.01.2023
Name & Signature (İsim/İmza) : **Kenan KILIÇ**
Board Chairman /Yönetim Kurulu Başkanı

KENMAK HASTANE MALZEMELERİ VE ELEKTROSATİK BOYA SAN. VE TİC. A.Ş.
SARNIÇ YOLU ÜZERİ NO: 23 GAZİEMİR – İZMİR / TURKEY

Tel: +90 (232) 274 1717

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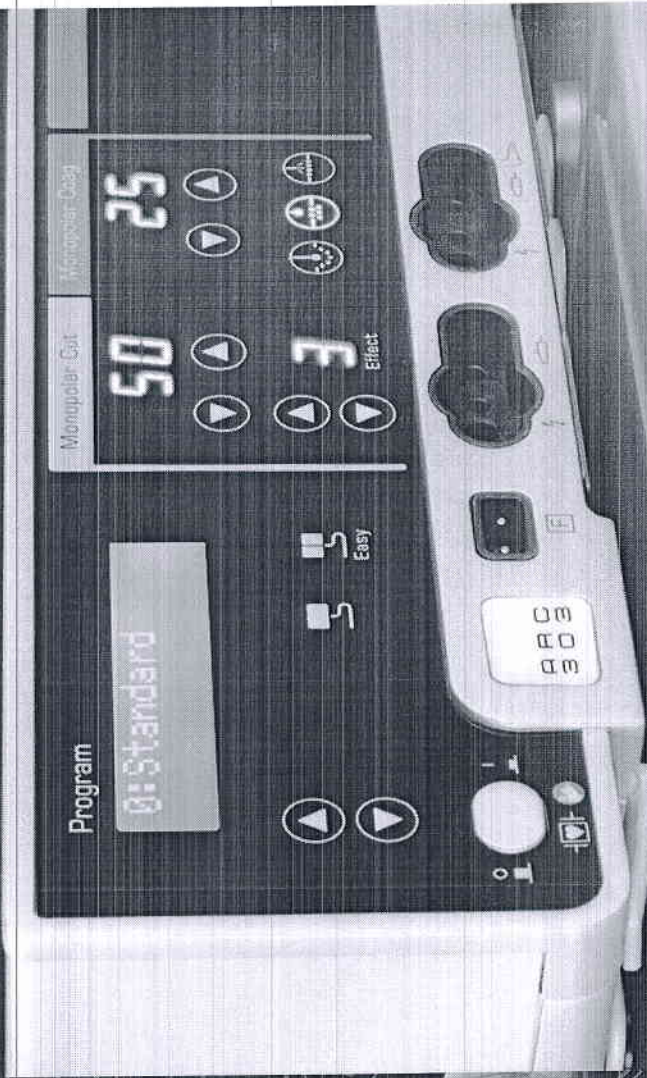
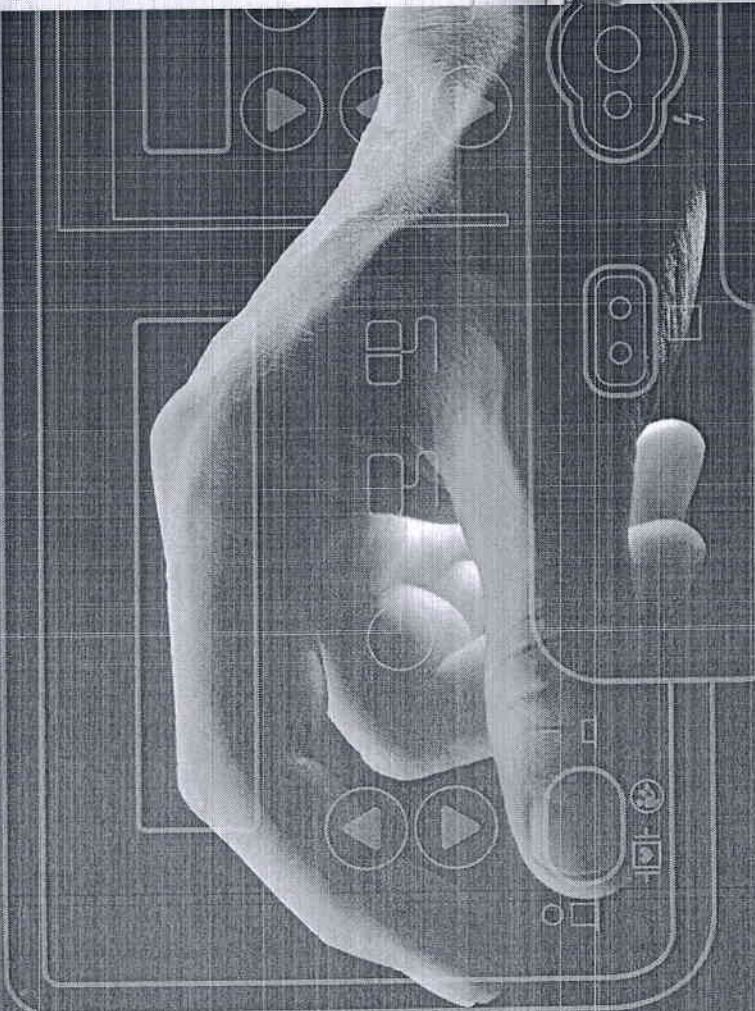
www.kenmak.com.tr

~ kenmak@kenmak.com.tr

1. Diatermocoagulator
Specificație completată
Model: ARC-303, Producător: BOWA Medical, Țara: Germania.

Dispozitiv electro-chirurgical (diatermocoagulator) cu accesorii specializate				
Parametrul	Specificația completă solicitată			Specificație tehnică completă propusă
Descriere	dispozitiv destinat pentru tăierea și coagularea țesuturilor biologice în procesul actului chirurgical care utilizează curenți electrici de frecvență înaltă			
Frecvența			cuprinsă între 300 KHz și 1 MHz	DA 330 KHz și 1 MHz
Canale de ieșire	Monopolar		izolat	DA 2 porturi
	Comutator de mână		da	DA
	Comutator de picior		tip pedală	DA
	Bipolar		da	DA
Moduri de lucru	Monopolar	Tăiere	Putere maximă- minim 300 W	DA 300 W
			Tensiune maximă- 2000V	DA
		Coagulare	Putere maximă- minim 120 W	DA 150 W
			Tensiune maximă- 4000V	DA
	Bipolar	Tăiere	Putere maximă- minim 80 W	DA 100W
			Tensiune maximă- 480V	DA
		Coagulare	Putere maximă- minim 50 W	DA 120 W
			Tensiune maximă- 300V	DA
Funcție de autotestare			da	DA la pornire, și continuu pentru electrodul neutru
Canal de ieșire independentă			da	DA
Indicatoare			acustic	DA
			vizual	DA
Control volum sunet			da	DA
Set accesorii pentru aplicații			Cablu pentru conectarea electrozilor activi autoclavabili -1buc	DA
			Cablu pentru conectarea electrodului neutru autoclavabil – 1 buc	DA
			Electrod neutru auroclavabil adulti- 1 buc	DA
			Ginecologice: Electrod tip ansa adulti autoclavabile – 1buc	DA
			Chirurgicale: Electrod p/u taere (tip cutit) autoclavabil- 1buc Electrod pentru cuagulare (tip pensa)-1 buc	DA
			Cablu pentru proceduri endochirurgicale- 1 buc	DA

ARC 303
ELEKTROCHIRURGIE-GERÄT
DER STARKE GENERALIST



BOWA
ARC 303

Der starke Generalist – ARC 303

Die 303 besitzt Leistungsstufen am Elektrostrahl, ummax. Schneiden und Koagulieren der Spitzenklasse in Neurologie, Herz- und Eingeweidechirurgie, Urologie, Gynäkologie und Orthopaedie.

Die Köhnen- sowie Monopolar-Einheiten sind abwaschbar, leicht montiert, angeschlossen werden. Es können alle elektrischen anreizschaltbar Grundfunktionen zur Verfügung.

Elektrotherapeutische Grundaufstellung zur Erledigung täglicher Aufgaben

Mittelschwere Gewebe-Effekte und stabile Leistungssteuerung:
Der ARC 303 bietet sämtliche elektrotherapeutische Standardmodi und sämtliche Funktionen wie AUTOSTART oder Stillhaltefunktion wie EASY. Neutrale Stromüberwachung über den integrierten Fehlerprüfer und automatisierten Belüfter. IBSYS.

Einfache Programmierung von zwei Handgriffen:
Bei verschiedenen Anwendungen im Bereich der Osteoporose 2 E-Motoren, in der Herz- und Lungentherapie 2 E-Motoren, in der Schmerztherapie 2 E-Motoren für die simultane Erzielung von Elektrotherapie an mehreren Stellen des Patienten erforderlich.

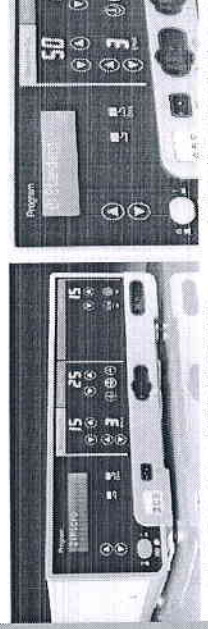
Intuitive, schnelle Bedienung:
Das monoskopische und der bipolare Ausgang werden jeweils über Direktwahltasten eingestellt. Alle Einstellungen werden an der Starttafel und im LCD-Display angezeigt.

Einfache programmierbare Einstellung und Steuerung ihrer persönlichen Programme:
Das LCD-Display zeigt das Programm an, mit dem man arbeiten möchte. Die Einstellungen für die verschiedenen Programme sind im Menü auszuwählen.

Anwendungsbereiche (Auswahl):
Allgemeine und viszerale Herz- und Lungentherapie, Bronchitis, Dyskardie, Urintherapie, Orthopädie und Unfallchirurgie, Kinderchirurgie

Programme:
Standard, Reaktion, Standard, Mehr, Misch.

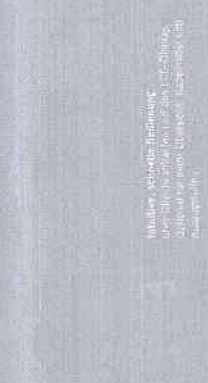
Das ARC 303 bietet Beweise in der Grundfunktion einer Funktion mit erhaltlichem Maßnahme.



Das Programm ARC 303 ist ein neues, innovatives Konzept, das die Leistung des Patienten verbessert und die Behandlung erleichtert.



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- Ideale Einsatzbereiche des ARC 303 in der HF-Chirurgie:
- Nieren-, Vesikel-, Harn-, Prostata- und Blasen-therapie
- Dyskardie
- Orthopädie und Unfallchirurgie
- Neurochirurgie
- Herzrhythmus

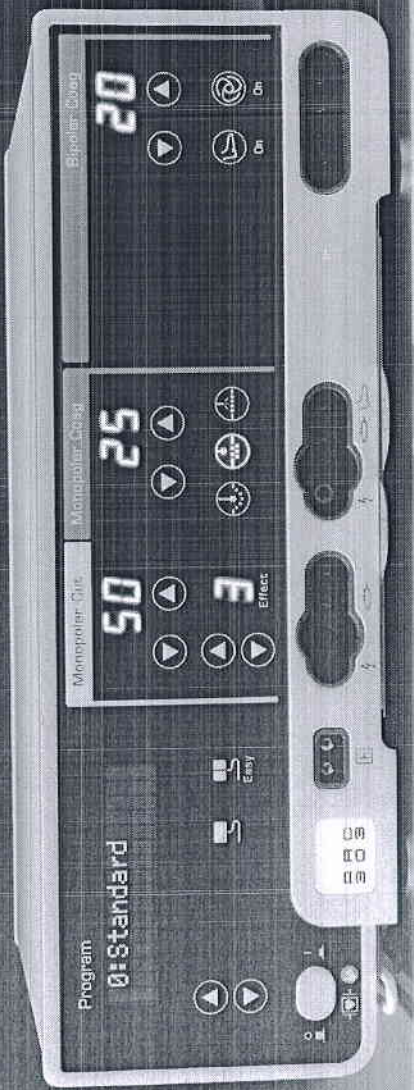
EINFACH SICHER – alle Einstellungen auf einen Blick

Das Programm ARC 303 ist ein neues, innovatives Konzept, das die Leistung des Patienten verbessert und die Behandlung erleichtert.

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ARC 303, REF. 900-003

ARC PLUS – das zündende Plus mit Argon-Unterstützung

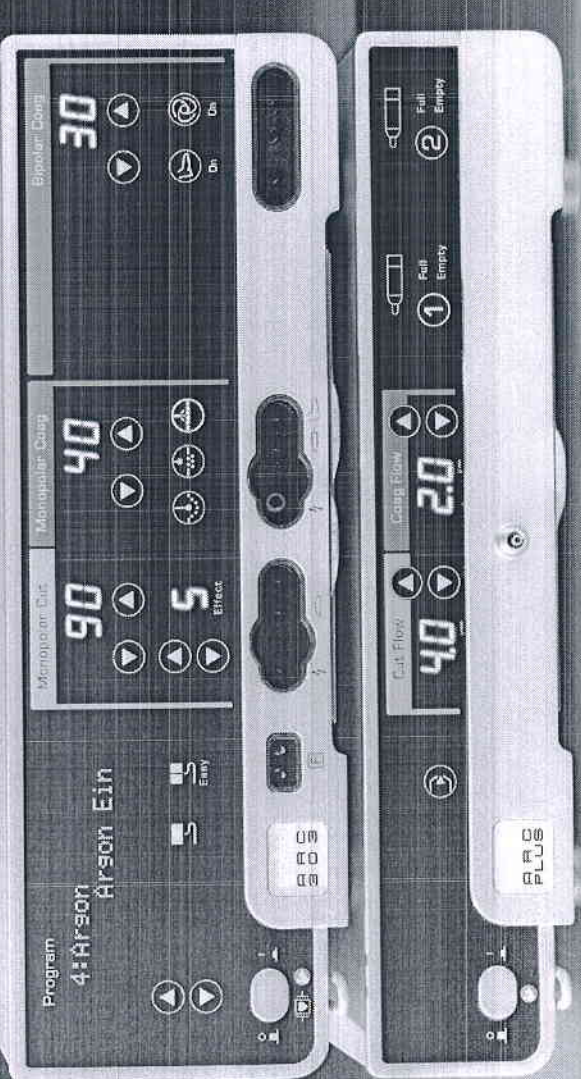
Bedienung: Sicher, Schnell, Effektiv

Die neue Generation von Argon-Plus eine elektrische Brücke zwischen Instrument und Gewebe herstellt. Die mit ARC PLUS enthaltene Argonzahl kann besonders gut dosiert und zur Kontaktflexibilität verbessert werden. Profitieren Sie von erhöhter Missionsfähigkeit durch schnelle, kontrollierte Koagulation mit maximaler Powerleistung und einfacher Dosierbarkeit.

Vorteile der ergonomischen Elektroschlinge in Chirurgie und Gynäkologie:

- Ergonomische Anheftung
- Schnelle Koagulation großer Flächen
- Karbonatleiste
- Hohe Sicht durch rauchfreie Koagulation
- Besonders einfache Handhabung durch großen Zündabstand > 10 mm und einfache Zündung

ARC PLUS REF 910-938



Argon-Workstation für einfaches Handling

- Effektives Handling
- Einfache Bedienung
- Ergonomische Anheftung
- Hohe Sicht durch rauchfreie Koagulation
- Besonders einfache Handhabung durch großen Zündabstand > 10 mm

Integriertes Messsystem

- Vollständige Messung
- Vollständige Messung
- Vollständige Messung

Robustes Gehäuse

- Robustes Gehäuse
- Robustes Gehäuse
- Robustes Gehäuse

ARC PLUS COAG und CUT

für ergonomisches Schneiden und Koagulieren bei offenen und laparoskopischen Anzeigengeräten in der Chirurgie und Gynäkologie:

- Außenaktivierung
- Laserfunktion
- Mammachirurgie
- Vaszektomie

Auch in der Endoskopie einsetzbar:

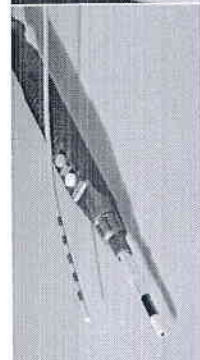
- Endoskopische Chirurgie
- Endoskopische Chirurgie
- Endoskopische Chirurgie



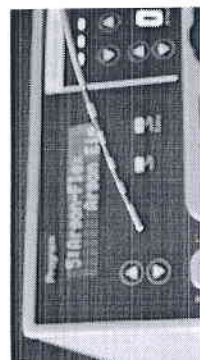
Anwendungsgebiete: (Auszug)

- Abdominale Chirurgie
- Abdominale Chirurgie
- Abdominale Chirurgie

Hersteller: ERBE Elektromedizin AG, Strümpfer 1, 78190 Pforzheim, Deutschland



ARC PLUS ist ein Produkt der ERBE Elektromedizin AG, Strümpfer 1, 78190 Pforzheim, Deutschland



ARC PLUS ist ein Produkt der ERBE Elektromedizin AG, Strümpfer 1, 78190 Pforzheim, Deutschland

Einfach anschließen – die BOWA-Zubehörteile

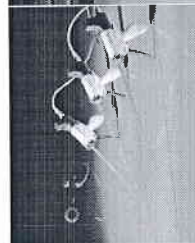
„EINFACH SICHER“ ist mehr als nur ein Versprechen. Es ist für uns die Verpflichtung, stets über den momentanen Standard hinauszugehen. Diese Haltung führt uns zu Lösungen, die neue Perspektiven aufzeigen und Sie in Ihrer Arbeit bestmöglich unterstützen.

Wenn Sie sich einen umfassenden Überblick über unser Leistungsprogramm verschaffen wollen, besuchen Sie uns auf www.bowamed.com

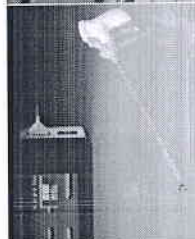
ARC 303 mit ARC 303-Kit



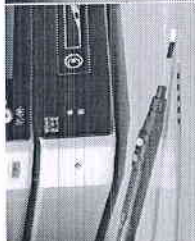
ARC 303



ARC 303 mit ARC 303-Kit



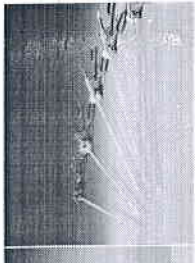
ARC 303 mit ARC 303-Kit



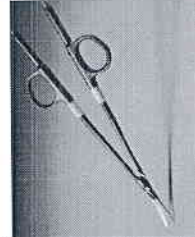
ARC 303 mit ARC 303-Kit



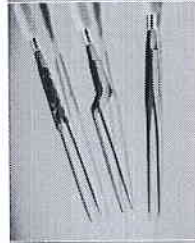
ARC 303 mit ARC 303-Kit



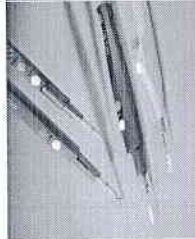
ARC 303 mit ARC 303-Kit



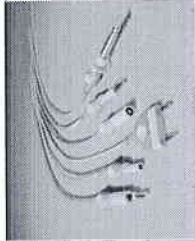
ARC 303



ARC 303 mit ARC 303-Kit



ARC 303 mit ARC 303-Kit



ARC 303 mit ARC 303-Kit



ARC 303 mit ARC 303-Kit



Einfach erweitern – Updates und Zubehör

Die Systeme sind softwarebasiert und damit lizenzierbar. In Verbindung mit dem BOWA-Zubehör komponiert sich der ARC 303 zu einem System mit Mehrwert – die medizintechnische Kontrolle können von einzelnen Krankenhausbereitern selbst durchgeführt werden.

Technische Informationen zu ARC 303

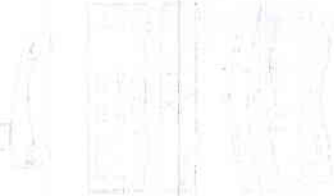
Der ARC 303 ist auf den Einsatz in allgemeinen Bereichen der Elektrotechnik ausgelegt. Die ARC-Elektrotechnik-Geräte können auf Deckenveringungseinheiten oder, zur uneingeschränkten Mobilität, auf dem Adapter montiert werden.

Technische Daten im Überblick	ARC 303	ARC PLUS
Maximale Leistung	100-250 VA	100-250 VA
Abgleichspanne	180-330 V/120-270 V	50-160 VA
Netzspanne	100-250 VA	50-160 VA
Leistungsfähigkeit	100-250 VA	50-160 VA
Leistungsfähigkeit in Standard-Modul	100-250 VA	50-160 VA
Leistungsfähigkeit in Standard-Modul (mit Adapter)	100-250 VA	50-160 VA
Leistungsfähigkeit in Standard-Modul (mit Adapter) (mit Adapter)	100-250 VA	50-160 VA
Leistungsfähigkeit in Standard-Modul (mit Adapter) (mit Adapter) (mit Adapter)	100-250 VA	50-160 VA
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Leistungsfähigkeit in Standard-Modul (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter)	100-250 VA	50-160 VA
Leistungsfähigkeit in Standard-Modul (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter) (mit Adapter)	100-250 VA	50-160 VA

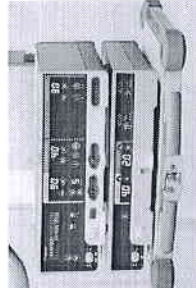
ARC CART – mehr Mobilität

Viele Einsatzmöglichkeiten In der Gesamtlösung bietet der ARC CART vier leistungsfähige Rollen mit Bremsen, Kabelschleife, Netz-Kabelabsicherung, Griff, Fußschalter und einen Kabelaufhänger. Der Abgesteck ist optimiert für den ARC-Generator.

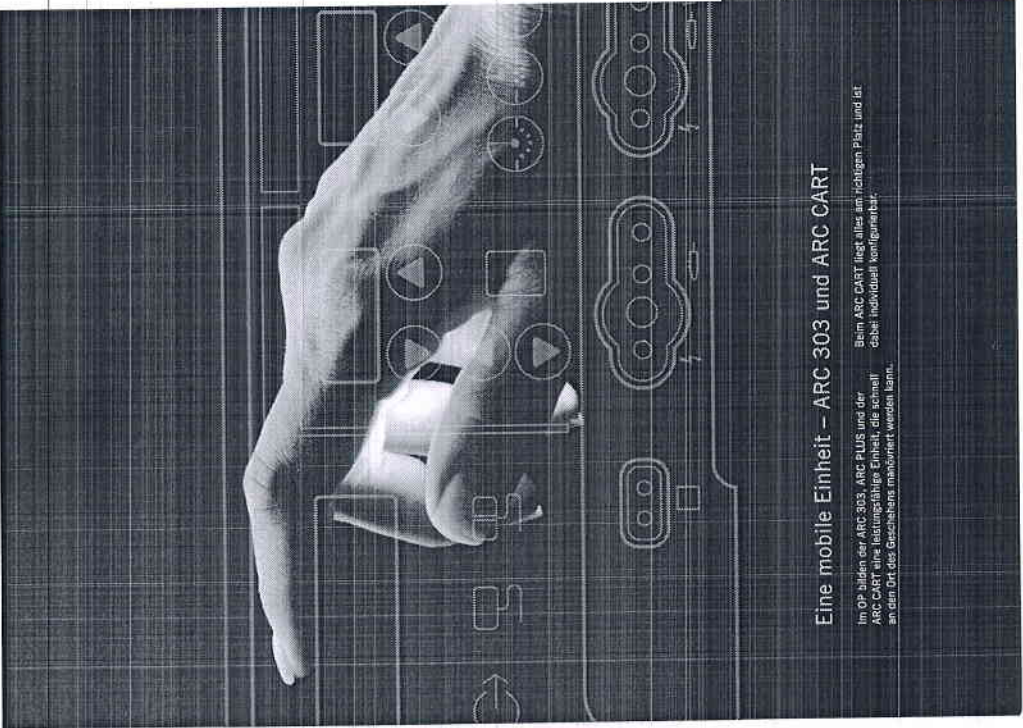
Als weitere Zubehör sind Ablagen z. B. für Tischhalter, Potentiometer, Schalter, Gas-Köpfe erhältlich. So entsteht ein richtiges Arbeitsplatz-System (PXB) mit höchster Flexibilität. Die Bedienelemente sind ergonomisch angeordnet, so dass sie längere und ermüdungsfreie Arbeiten erlauben.



Der ARC CART gewährleistet eine mehrstufige Augen-Optimierung im 3D-ansichtsbereich.



Die Einheit des ARC PLUS ist für die ARC PLUS-Modulare auf einer mobilen Bedienungsstation.



Eine mobile Einheit – ARC 303 und ARC CART

Im 3D-Bild des ARC 303, ARC PLUS und der ARC CART, eine leichtgewichtige Einheit, die schnell an den Ort des Einsatzes transportiert werden kann.

Beim ARC CART liegt alles am richtigen Platz und ist dabei individuell konfigurierbar.

BOWA
EINFACH SICHER

BOWA-electronic GmbH & Co. KG
Halmerei-Hertz-Straße 4-10
72810 Gomadingen 1, Germany

Telefon: +49 (0) 7072 69 22 0
Telefax: +49 (0) 7072 69 22 33
info@bowa.de | bowa-merkmale.com



**1. Monitor pentru monitorizarea funcțiilor vitale(cardiomonitor
 Specificație completată
 Model: CMS-8000, Producator: Gima, Tara: China.**

Monitor pentru monitorizarea funcțiilor vitale (caracteristici de baza cu accesorii Adult,Pediatric)				
Descriere	Sistem pentru monitorizarea și afișarea funcțiilor vitale ale pacientului cu caracterisitici de bază.			
Parametrul		Specificație propusă	Specificația completată	
Tip pacient	Adult,pediatric, nou-născut	da	Da	
Display, tip	Diagonala	≥ 12 inch	Da 12,1 inch	
	LCD TFT sau LED	da	Da LCD TFT	
	Numărul de curbe afișate concomitent	între 3 și 12 minim	DA 8	
	Parametri afișați	Semnal ECG		DA
		Pulsul		DA
		SpO2		DA
		Fotopletismograma		DA
		Presiunea sanguină neinvaziv		DA
Temperatura		Da		
Analiza automată a undei ST	Trendingul ST	da	DA	
	Media în analiza segmetului ST	da	DA	
Modul ECG	Culegerea semnalului ECG prin cablu 3 electrozi	da	DA	
	I, II, III	da	DA	
	Sensivitatea	2.5 - 40 mm/mV	DA	
	Gama de rejecție a modului comun la 50 Hz	≥ 100 dB	DA	
	Rata cardiacă	Interval minim 15 - 300 bpm	DA	

	Detectarea aritmiei	da	DA
	Detectarea pacemaker	da	DA
	Monitorizarea respirației Adult	minim 0 - 120 rpm	DA 0- 150 rpm
	Monitorizarea respirației Pediatric	minim 0 - 150 rpm	Da
	Protecție înotriva șocurilor de defibrilare	da	Da
Modul SpO2	Diapazonul	1 - 100%	Da 0- 100 %
	Acuratețea la 70 - 100%	≤ 2 %	Da
	Monitorizarea rata pulsului	Minim 30 - 300 bpm	Da
	Monitorizarea pletismogramei	da	DA
	Sa se indice tehnologia modulului și senzorului de SpO2 utilizat	<i>(exemplu: masimo, nellcor, etc)</i>	DA
Modul NIBP	Diapazonul Adult	10 - 270 mmHg	DA
	Diapazonul Pediatric	10 - 200 mmHg	DA
	Regim de măsurare	manual, automat, butonul Start	DA
	Regim automat	Nu mai rar de 5, 10, 15, 30, 60, 120 min.	DA
	Buton de activare/dezactivare manual a NIBP	da	DA
	Metoda de măsurare	oscilometrică	DA
	Regim pacient	Adult, pediatric, nou-născut	DA
	Protecție de suprapresiune la regimului de pacient adult	300 mmHg	DA
	Protecție de suprapresiune la regimului de pacient	240 mmHg	DA

Anexa 9

	pediatric		
Modul Temperatura	Diapazonul	Minim 0 - 50.0 °C	DA
	Rezoluția	Minim 0.1 °C,	DA
	Număr de senzori	1 unit.	DA
Protocole de lucru preprogramate		da	DA
Protocole de lucru setate de utilizator		da	DA
Memorie internă		da	DA
Trendingul evenimentelor		da	DA
Arhivarea datelor		da	DA
Imprimantă	Încorporată	da	DA
Forme de raportare	Viteza de înscriere	Minim 25, 50 mm/s	DA
	Înscriere continuă	da	DA
	Preprogramate	da	DA
	Personalizate	da	DA
Alimentarea	rețea electrică 220 V, 50 Hz	da	DA
	Baterie internă	da	DA
	Timp de lucru autonom a bateriei	minim 2 h	DA 2 h
Interfata de conectare la monitorul central	Ethernet / wireless / RS-232 / etc.	da	DA Ethernet si RS-232
Alarma	Vizuala, sonora		DA
	Manjetă deconectată	da	DA
	Manjetă defect	da	DA
	Senzor SpO2 deconectat	da	DA
	Senzor SpO2 defect	da	DA
	Alarmă concentrația SpO2 scăzută/mărită	da	DA
	Nivelul baterie scăzut	da	DA

	Alarmerata cardiacă scăzuta/mărită	da	DA
	Lipsă sursă externă de alimentare	da	DA
	Buton de dezactivare/anulare alarmerasonore	da	DA
	Ajustareanivelului de alarmă	da	DA
Accesorii			
Cablu ECG	cu 3 electrozi	2 buc.	DA
Electrozi ECG	<u>adult, unică utilizare</u>	<u>300 buc.</u>	<u>DA</u>
	<u>pediatric,unică utilizare</u>	<u>300 buc.</u>	
Senzor SpO2	<u>adult, reutilizabil tip cleste</u>	<u>2 buc.</u>	<u>DA</u>
	<u>pediatric,reutizabil</u>	<u>2 buc.</u>	
Senzor Temperatură	reutilizabil	1 buc.	DA
	Adult mediu,adult,adult mare reutilizabile (1 set/3 buc)	2 set.	DA
Manjete NIBP	Pediatric,pediatric mediu,pediatric mare reutilizabil (1set/3buc)	2 set.	DA
Hîrtie termică		5 buc.	DA
Suport pe rotile (să se indice modelul suportului)	4 rotile	da	DA
	min. 2 rotile cu frînă	da	DA
	coș pentru accesorii	da	DA
	mîner pentru transportare	da	DA
	sistem de fixare a dispozitivului de suport	da	DA



GIMA

CMS 8000 MULTIPARAMETER PATIENT MONITOR

Code: 35151

Category: Patient monitors Vital Sign and accessories

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: II B

NSIS: 402941

CND: Z1203020201

EAN13: 6945040100034

Description: CMS 8000 PATIENT MONITOR ECG, RESP, SpO2, PR, NIBP, DUAL CHANNEL TEMP

- 12.1" TFT colour LCD display
- multilanguage interface (GB, IT, FR, DE, ES, PT, NL, PL, CZ, TR, RO, RU)
- adult/pediatric/neonate measurement modes
- 8 channel waveform synchronous display
- 7 lead ECG waveform on one screen
- anti-motion, anti-ambient light interference digital SpO2 technology
- AC/DC rechargeable lithium battery
- manual/AUTO/continuous NIBP measurement mode
- standard/OXY- graph/Trend-graph/big characters and view bed interfaces

Technical Specifications:

• ECG

5-lead, dual channel, 3-lead, single channel
Scan speed: 12.5 mm/s, 50 mm/s
ST segment monitoring
Measurement and alarm range: -2.0 mV ±2.0 mV

• RESP

Method: R-F (RA-LL) impedance
Measurement and alarm range: 0-150 rpm
Apnea alarm: 10-40 sec

• NIBP - Oscillometric method

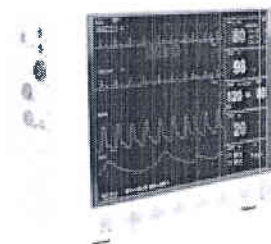
Mode: manual/AUTO/continuous
Measurement interval in AUTO mode: 1/2/3/4/5/10/15/30/60/90/120/240/480/960 min
Measurement period in CONT mode: 5 min
Measurement alarm: 10-270 mmHg

• SpO2

Measurement and alarm range: 0-100%
Measurement accuracy: 70-100% ±2%

• PR

Measurement and alarm range: 30-250 bpm





GIMA

• **TEMP**

Channel: dual channel

Measurement and alarm range: 0-50 °C

Power supply: 110-240 V - 50/60 Hz


Safety classification: Classe I type CF

Defibrillation-proof applied part

Standard accessories:

- Adult SpO2 probe
- NIBP adult cuff and extension tube
- Temperature probe - skin
- Rechargeable lithium battery
- ECG cable
- Power supply cable
- Manual (GB, IT, ES) on request (PT, TR)
- ECG electrodes

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

 <p>MANUFACTURER:</p>	<p>CONTEC MEDICAL SYSTEMS CO., LTD No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA</p>
<p>MEDICAL DEVICE:</p>	<p>Patient Monitor , CMS8000</p>
<p>CLASSIFICATION - ANNEX IX:</p>	<p>Class II b, Rule 10</p>
<p>CONFORMITY ASSESSMENT ROUTE:</p>	<p>Annex II excluding chapter 4</p>
<p>GMDN CODE:</p>	<p>33586</p>
<p>We, (CONTEC MEDICAL SYSTEMS CO., LTD) herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC All supporting documentation is retained at the premises of the manufacture.</p>	
<p>Standards applied: see attached list of (harmonised - EN) standards for which documented evidence of compliance can be provided.</p>	
<p>NOTIFIED BODY:</p>	<p>TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany</p>
<p>IDENTIFICATION NUMBER:</p>	<p>CE 0123</p>
<p>(EC) CERTIFICATE(S):</p>	<p><u>G1 050972 0050 REV.01</u></p>
<p>EC REP</p>	<p>Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany</p>
<p>EUROPEAN REPRESENTATIVE:</p>	

START OF CE-MARKING: 2010-3-20 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION: QINHUANGDAO, 2019-03-21

SIGNATURE:  President

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**

No.	Serial Number	Title and Description
1	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
2	IEC 62304:2015	Medical device software - Software life-cycle processes
3	EN ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices. Evaluation and testing
4	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
5	IEC60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
6	IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
7	IEC60601-1-8:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
8	IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
9	IEC 80601-2-30:2009	Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
10	IEC 60601-2-34:2011	Medical electrical equipment -Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
11	IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
12	ISO 80601-2-55:2011	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors
13	ISO 80601-2-56:2009	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
14	ISO 80601-2-61:2011	Medical electrical equipment -Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.bfarm.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. **G1 050972 0050 Rev. 01**

Manufacturer: **Contec Medical Systems Co., Ltd.**
No.112 Qinhuang West Street
Economic & Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Patient Monitor, Fetal Monitor, B-Ultrasound Diagnostic System, Pulse Oximeter, Electrocardiograph, Pocket Fetal Doppler, Visual Electronic Stethoscope, Multi-functional Visual Stethoscope, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Portable ECG Monitor, Temperature Probe, Pulse Oximeter Probe, Tele Pulse Oximeter, Tele Breather, Multi-parameter Vital Signs Monitor, Sleep apnea screen meter, Oxygen concentrator, ECG Workstation, Wearable Monitor.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **BJ1890204**
Valid from: **2019-03-08**
Valid until: **2019-07-22**
Date, **2019-03-08**

Stefan Preiß

Anexa nr.10 Otoscop		
Descriere	Otoscop – dispozitiv care permite examinarea conductului auditiv al timpului într-un mod rapid și precis.Dispune de lupa pentru amplificarea de până la 3 ori a distanței focale.Are o fereastă largă de vizionări.	
Parametrul	Specificația solicitata	Specificația tehnica oferita 01.12830.101 (Kawe /Germania)
Tip	portabil	portabil
Sistem iluminare	LED	LED
Accesorii	Specule multiple de diferite dimensiuni	Specule de diferite dimensiuni: d.2.5mm-10 buc d.4mm-10 buc
Alimentare	Baterie reincarcabila	Baterie reincarcabila Li-ion
Incarcator la retea 220V,50 Hz	da	Da (12.80005.002)

Anexa nr.11 Oftalmoscop				
Descriere		Oftalmoscop-dizpozitiv pentru examinarea fundului de ochi		
Parametrul		Specificația solicitata	Specificatia tehnica oferita 01.25361.101 E36 (EU) 3,5 V (Kawe /Germania)	
Tip		portabil	portabil	
Diapazon focusare		-20+20 D	-20+20 D	
Pasii de dioptrii		1-10 cu pasul de 1D;15;	1-10;15;20	
Sistem iluminare		LED	XH	
5 fante	Spot mare	da	da	6 fante
	Spot mic	da	da	
	Jumatate de spot	da	da	
	Filtru rosu	da	Stea de fixare	
	Filtru verde	da	da	
Alimentare		Baterie reincarcabila	Baterie reincarcabila Li-ion	
Incarcator la retea 220V,50 Hz		da	Da (12.80005.002)	

KaWe COMBILIGHT®



KaWe COMBILIGHT® F.O.30 3,5 V

- Clic-Verschluss
- leistungsstarke 3,5 V Xenon-Lampe
- Metall-Ladegriff C
- Rheostat dimmbar
- Einweg-Ohrtrichter (»22)
- 10 x Ø 2,5 mm, 10 x Ø 4,0 mm
- inkl. Li-Ion Ladebatterie 3,5 V nur in Verbindung mit Ladestation KaWe MedCharge® 4000 verwendbar (»208)
- in Reißverschlusstasche

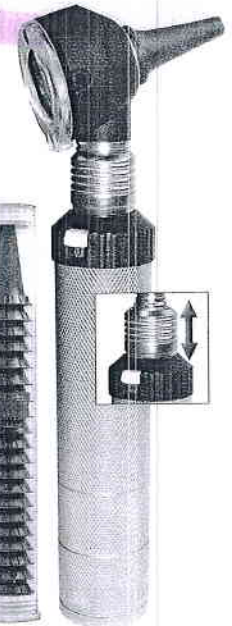
- click-on connection
- high power 3.5 V xenon bulb
- metal charging handle C
- dimmable rheostat
- disposable ear funnels (»22)
- 10 x Ø 2.5 mm, 10 x Ø 4.0 mm
- incl. 3.5 V Li-ion rechargeable battery (only to be used with KaWe MedCharge® 4000 charging station (»208)
- in bag with zipper



KaWe COMBILIGHT® F.O.30 LED 3,5 V

- Clic-Verschluss / LED-Lampe
- Beleuchtungsstärke ca. 20.000 Lux
- Lebensdauer Lampe ca. 50.000 h
- Metall-Ladegriff C
- Einweg-Ohrtrichter (»22)
- 10 x Ø 2,5 mm, 10 x Ø 4,0 mm
- inkl. Li-Ion Ladebatterie 3,5 V nur in Verbindung mit Ladestation KaWe MedCharge® 4000 verwendbar (»208)
- in Reißverschlusstasche

- click-on connection / LED bulb
- illuminance approx. 20,000 Lux
- lifetime approx. 50,000 h
- metal charging handle C
- disposable ear funnels (»22)
- 10 x Ø 2.5 mm, 10 x Ø 4.0 mm
- incl. 3.5 V Li-ion rechargeable battery (only to be used with KaWe MedCharge® 4000 charging station (»208)
- in bag with zipper



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F.O.30 | 3,5 V | XL REF 01.12430.101

Leuchtmittel | illuminant

REF 12.75241.003 (28925)

5 F.O.30 LED | 3,5 V | LED REF 01.12830.101

Leuchtmittel | illuminant

REF 12.75253.003



KaWe COMBILIGHT® F.O.30 3,5 V

- Clic-Verschluss
- **aufladbar in Steckdose** (EU 240 V)
- leistungsstarke 3,5 V Xenon-Lampe
- Metall-Ladegriff C
- Rheostat dimmbar
- Einweg-Ohrtrichter (»22)
- 10 x Ø 2,5 mm, 10 x Ø 4,0 mm
- inkl. NiMH Ladebatterie 3,5 V
- in Reißverschlusstasche

- click-on connection
- **rechargeable in electric outlet** (EU 240 V)
- high-power 3.5 V xenon bulb
- metal charging handle C
- dimmable rheostat
- disposable ear funnels (»22)
- 10 x Ø 2.5 mm, 10 x Ø 4.0 mm
- includes 3.5 V NiMH rechargeable battery
- in bag with zipper



6 F.O.30 | 3,5 V | XL **EU** REF 01.12430.811 (26550)

Leuchtmittel | illuminant

REF 12.75241.003 (28925)

aufladbar in Ladestation KaWe MedCharge® 4000 in Verbindung mit Ladebatterie / rechargeable in KaWe MedCharge® 4000 charging station with rechargeable battery
Ladebatterie im Lieferumfang enthalten / rechargeable battery is included


XL Xenon-Lampe / xenon bulb
LED LED-Lampe / LED bulb



KaWe EUROLIGHT®

FAMILIE | PRODUCT LINE

KaWe EUROLIGHT® E36

- Clic-Verschluss
- 2,5 V Xenon/Halogen-Lampe
- Metall-Batterie-/Ladegriff C
- Rheostat dimmbar
- mit Korrektionslinsenrad stufenweise von +20 bis -20 Dioptrien
- in Reißverschluss tasche
- Batterien: 2x Baby 1,5 V (Typ C) 
- 6 Blenden, hervorragende und gleichmäßige Ausleuchtung! Sehr großes Untersuchungsfeld des Augenhintergrundes.

- click on connection
- 2.5 V xenon/halogen bulb
- metal battery/charging handle C
- dimmable rheostat
- with lens correction dial
- incremental steps from +/- 20 dioptres
- in bag with zipper
- batteries: 2 C batteries, 1.5 V
- 6 apertures, good and uniform illumination! Very large examination field of the fundus of the eye.

 E36 | 2,5 V | XH   REF 01.21361.001 (27070)

 E36 | 2,5 V | XH   REF 01.21366.001 (27080)

Leuchtmittel | Illuminant REF 12.75132.003 (28946)



6 Blenden | 6 apertures

Grünfilter
Green filterBlaufilter
Blue filter

KaWe EUROLIGHT® E36

Merkmale:

- direkte Ophthalmoskopie
- mit sechs Blenden für vielseitige ophthalmologische Untersuchungen
- Blendenrad mit 18 Korrektionslinsen von +20 bis -20 Dioptrien
- asphärische Präzisionsoptik
- robust

Features:

- direct ophthalmoscopy
- with six apertures for all types of ophthalmoscopic examinations
- aperture selection dial with 18 correction lenses from +20 to -20 dioptres
- aspherical precision optics
- robust

KaWe EUROLIGHT® E36 3,5 V

- Clic-Verschluss
- leistungsstarke 3,5 V Xenon/Halogen-Lampe
- Metall-Ladegriff C
- Rheostat dimmbar
- mit Korrektionslinsenrad stufenweise von +20 bis -20 Dioptrien
- inkl. Li-Ion Ladebatterie 3,5 V nur in Verbindung mit Ladestation KaWe MedCharge® 4000 verwendbar (►208)
- in Reißverschluss tasche

6 Blenden, hervorragende und gleichmäßige Ausleuchtung! Sehr großes Untersuchungsfeld des Augenhintergrundes.

- click-on connection
- high-capacity 3.5 V xenon/halogen bulb
- metal charging handle C
- dimmable rheostat
- with lens correction wheel
- incremental steps from +/- 20 dioptres
- incl. 3.5 V li-ion rechargeable battery (only to be used with KaWe MedCharge® 4000 charging station (►208)
- in bag with zipper

6 apertures, good and uniform illumination! Very large examination field of the fundus of the eye.

 E36 | 3,5 V | XH   REF 01.25361.101

Leuchtmittel | Illuminant REF 12.75232.003 (28923)



Lithium-Ion Battery
151P ICR 18650A
www.kawe.de
KaWe
GERMANY

3,5V NEW

KaWe EUROLIGHT® E36 3,5 V

- Clic-Verschluss
- aufladbar in Steckdose (EU 240 V)
- leistungsstarke 3,5 V Xenon/Halogen-Lampe
- Metall-Ladegriff C
- Rheostat dimmbar
- inkl. NiMH Ladebatterie 3,5 V
- in Reißverschluss tasche
- 6 Blenden, hervorragende und gleichmäßige Ausleuchtung! Sehr großes Untersuchungsfeld des Augenhintergrundes.




- click-on connection
- rechargeable in electric outlet (EU 240 V)
- high-power 3.5 V xenon/halogen bulb
- dimmable rheostat
- includes rechargeable battery 3.5 V
- in bag with zipper
- 6 diaphragms, good and uniform illumination! Very large examination field of the fundus of the eye.

 E36 | 3,5 V | XH   REF 01.25361.811

Leuchtmittel | Illuminant REF 12.75232.003 (28923)



Rechargeable battery
NiMH recharge
REF 12.80120.742
NIMH
3.5 V

 aufladbar in Ladestation KaWe MedCharge® 4000 in Verbindung mit Ladebatterie / rechargeable in KaWe MedCharge® 4000 charging station with rechargeable battery
 Batterien sind nicht im Lieferumfang enthalten! / Batteries are not included!
 Ladebatterie im Lieferumfang enthalten! / rechargeable battery is included!

XH Xenon/Halogen-Lampe / xenon/halogen bulb

KaWe MedCharge® 4000

LADESTATION | CHARGING STATION

KaWe MedCharge® 4000 ist die Ladestation für die Metallgriffe der KaWe EUROLIGHT®, KaWe COMBILIGHT®- und Laryngoskop-Linie in kleiner (AA) und mittlerer (C) Ausführung, ausgenommen der Economy-, LED 2,5 V und Stecker-Ladegriffe.

Intelligente Elektronik überwacht den Spannungsverlauf der Ladebatteriezellen beim Ladevorgang. Dadurch wird eine Überladung der Ladebatterien verhindert und die Lebenszeit der einzelnen Ladebatterien optimal ausgenutzt. KaWe MedCharge® 4000 erkennt den Ladebatterietyp sowie seinen Ladezustand und passt dank Microcontrol-System den Ladezustand individuell an. Die Ladestation KaWe MedCharge® 4000 verfügt über eine integrierte, automatische Abschaltung.

Die Betriebsdauer einer Ladebatterie mittlerer Größe liegt bei ca. drei Stunden, bei der kleineren Ausführung bei ca. zwei Stunden; diese ist abhängig vom Leuchtmittel.

KaWe MedCharge® 4000 is the charging station for the KaWe EUROLIGHT®, KaWe COMBILIGHT®, and the laryngoscope product lines metal handles in small (AA) and medium (C) models, with the exception of the Economy, LED 2.5 V and plug-in charging handles.

Intelligent electronics control the progress of the rechargeable battery cells during the charging process thus preventing them from overcharging and ensuring that the service life of each individual rechargeable battery is optimally utilized. The KaWe MedCharge® 4000 uses a micro-control system to recognize the rechargeable battery type as well as its state of charge and adjusts for each individual charge level using a micro-control system. The KaWe MedCharge® 4000 charging station has a built-in automatic shut-off function.

The operation time of a medium-sized rechargeable batteries is approximately 3 hours, whereas the smaller models last approx. 2 hours. This is however, dependent on the type of bulb used.

KaWe MedCharge® 4000 | KaWe MedCharge® 4000

Ladestation, komplett mit Netzteil und wechselbarem Netzstecker für die Lithium-Ion-Technologie
 Charging station, complete with power supply unit and universal power plug for Lithium-ion technology

Lieferumfang:

- Netzstecker
EU 240 V / GB 240 V / US 110 V
- 2 Adapterhülsen für Griffe (AA)
- Wandhalter

Scope of supply:

- power plug
EU 240 V / GB 240 V / US 110 V
- 2 adapter sleeves for (AA) handles
- wall-mounted holder

Auswahl verschiedener Netzstecker für 2,5 V und 3,5 V Ladegriffe
 Selection of different power plugs for 2.5 V and 3.5 V charging handles

ALL IN ONE



Netzstecker | power plug

REF 12.80005.002

Leistungsmerkmale:

Eingangsspannung	100 V - 240 V +/- 10%, 50 - 60 Hz
max. Netzstrom	1,2 A
Wirkungsgrad	90 - 93 %
Ladbare Kapazität	min. 250 mAh, max. 4500 mAh
Eingangsspannung Ladestation	9 VDC +/- 10 %
Ausgangsspannung im Leerlauf	9 VDC
Nenn-Ausgangsspannung	2x 3,6 VDC
Nenn-Ladestrom	2x 250 mA +/- 10 %
Ladeschlussstrom	10 - 30 mA für Li-Ion
Spannungsfestigkeit	4 kV
Schutzklasse	II
Betriebstemperatur	0° C - +40° C
Lagertemperatur	-25° C - +70° C



Wandhalter
Wall mounting bracket

für 2,5 V und 3,5 V KaWe-Ladebatterien
 NiMH, Li-Ion (NiCd)
 for 2.5 V and 3.5 V NiMH, Li-Ion (NiCd)
 KaWe rechargeable batteries

Performance characteristics:

input voltage	100 V - 240 V +/- 10%, 50 - 60 Hz
max. power	1.2 A
efficiency factor	90 - 93 %
chargeable capacity	min. 250 mAh, max. 4500 mAh
input voltage charging station	9 VDC +/- 10 %
output voltage in stand-by	< 9 VDC
rated output voltage	2x 3.6 VDC
rated charging current	2x 250 mA +/- 10 %
charge end power	10 - 30 mA for Li-Ion
electric strength	4 kV
safety rating	II
operating temperature	0° C - +40° C
storage temperature	-25° C - +70° C

208

CERTIFICATE

No. 490115



This is to certify that the Quality Management System of Medical Devices of



KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstr. 56
71679 Asperg
Germany

has been assessed and found to be in compliance with the standard

ISO 13485:2016

applicable to

Development, production and sales of medical devices for general medicine, otolaryngology, ophthalmology, anesthesiology and dermatology.

The certificate has been issued under No. **490115** for the registration period from 16th February 2018 to 15th February 2021.


Approved by


Printed by

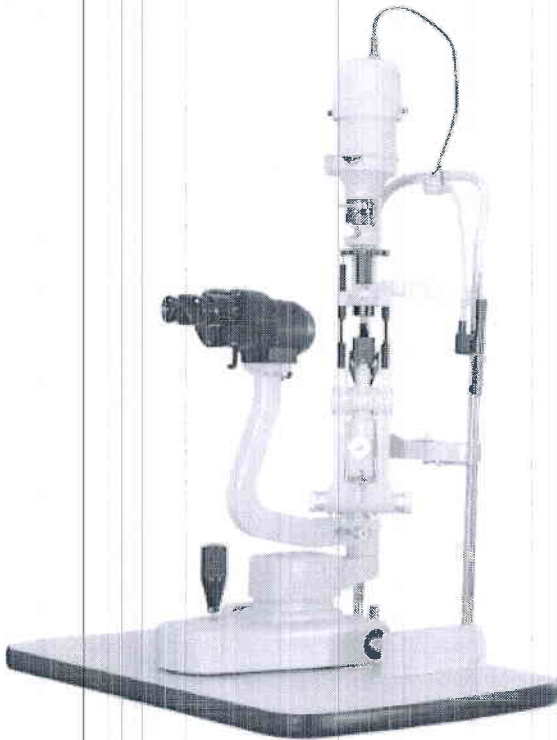


validity code: **BEEAA4C4-DD7**
Check the validity of this certificate using this code at www.ll-c.info

Anexa 11 **Lampa cu fanta**

Microscop binocular care permite examinarea stereoscopică detaliată a structurilor oculare		
Parametru	Specificația	Specificatia tehnica SLM-1ER,
Sistemul de iluminare Lățimea fantei,	mm 0-10 minimum, adjustabilă	mm 0≈14 minimum, adjustabilă
Sistemul de iluminare Lungimea fantei	mm 0-10 minimum, adjustabilă	mm 0≈14 minimum, adjustabilă
Rotirea	grade 0-90 maximum	grade 0~180
Filtre	Minim: albastru, verde, absorbție de căldură	albastru, verde, absorbție de căldură, sur
Microscopul Tipul	Binocular	Binocular
Mărire totală	10x minimum	10x ,16x
Gama de reglare a dioptriei,	dioptrii de la -7 la +7 minim	dioptrii de la ±7 la ±15 minim
Gama de mișcare	Deplasare laterală, mm ≥100	Deplasare laterală, mm 100
	Deplasare în adâncime, mm ≥100	Deplasare în adâncime, mm 90
	Deplasare în înălțime, mm ≥30	Deplasare în înălțime, mm 30
	Reglare fină de la joystick, mm ≥±10	Reglare fină de la joystick, mm 15
	Reglarea înălțimii bărbiei, mm ≥ 70	Reglarea înălțimii bărbiei, mm 80
Alimentarea, 220 V, 50 Hz	da	da
Accesorii	Setul standard	Setul standard
	Bec -2 buc	Bec -2 buc

SLM-1ER Slit Lamp halogen bulb



Characteristics:

- Two-step magnifications: 10×、16×
- All the Optical lenses are moistureproof, mildewproof and anti-reflected treated.
- Excellent optical performances.
- Convenient and compact.

It is a good machine for glasses shop.

Microscope Type	Converging stereoscope microscope
Objective Magnification	Two Steps Magnifications
Eye Piece	10x
Magnifications (Field of View)	10x (ϕ 18mm) 、 16x (ϕ 14.5mm)
Pupil Distance	55mm~82mm
Diopter Adjustment	\pm 7D
Slit Width	0mm~14mm adjustable
Slit Height	1mm~14mm adjustable
Aperture of Diameter	ϕ 9mm、 ϕ 8mm、 ϕ 5mm、 ϕ 3mm、 ϕ 2mm、 ϕ 1mm、 ϕ 0.2mm
Slit Angle	0°~180° adjustable
Slit Inclination	5° , 10° , 15° , 20° , four steps adjustable
Diameter of Light Spot	ϕ 9mm、 ϕ 8mm、 ϕ 5mm、 ϕ 3mm、 ϕ 2mm、 ϕ 1mm、 ϕ 0.2mm
Filter	Heat Absorption、 Grey、 Redfree、 Cobalt Blue
Illumination Bulb	12V/30W Halogen Bulb

Input Voltage	AC220V±22 V ;AC110V±11 V
Electrical Safety Standard	Executive Standard:IEC601-1,Class I,Type B
Packing Volume	720mm × 495mm x 480mm
Total Weight	23Kg
Optional Accessories	R type , T type Applanation Tonometer、 Measuring Eye Piece、 Trihedron Lens、 Gonioscope、 Funduscope、 Aspheric Lens

DECLARATION OF CONFORMITY



We, the manufacturer:

NANJING REDSUN OPTICAL CO.,LTD.
NO.18-304 SOUTH OF XISHANGQIAO ROAD OF NANJING,JIANGSU,CHINA

EU Representative: EU Representative:

LUXUS LEBENSWELT GMB

Address: KOchstr.1, 47877, Willich, Germany

Declare under our sole responsibility that:

Product: SLM-3ER, SLM-1, SLM-2L, SLM-2, SLM-4, SLM-4+, SLM-4X

Product Group: SLM Ophthalmic slit lamp

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)

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:

何

Export Sale Manager

2017-7-5

Authorized Signature



DNV BUSINESS ASSURANCE MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 54098-2009-AQ-RGC-NA

This is to certify that the Management System of:

Nanjing Redsun Optical Co., Ltd.

NO.18 of Cishan Road of Yuhua, Nanjing, China

has been found to conform to the standard:

ISO 9001:2015

This Certificate is valid for the following product or service ranges:

Design, Development, Manufacture and Servicing of Ophthalmic Optical Diagnostic Equipment, Ophthalmic Surgical Instruments, Ophthalmic Electrical Treatment Devices, Intraocular Lenses and Accessories, Medical Laser Ophthalmic Treatment Systems, Medical Sodium Hyaluronate Gel and Ophthalmic Curer for Iontophoresis Electrotherapy, Auto refractometer, Auto lensmeter, Auto lens edger

Initial Certification date:

23 April, 2015

This Certificate is valid until:

23 April, 2021

The audit has been performed under the supervision of

Jin Ming Xu
Lead Auditor

Place and date:

23 April, 2018

for the Accredited Unit:
**DET NORSKE VERITAS
CERTIFICATION AS, NORWAY**

Eugenie Winger Husebye
Management Representative



Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
This Certificate has been digitally signed. See www.dnv.com/digitalcertificates for more info.

HEAD OFFICE: Det Norske Veritas AS, Veritovenn 1, 1322 Sjøvik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 - www.dnv.com