Digitally signed by Cojocaru Vera
Date: 2023.09.12 16:53:31 EEST
Reason: MoldSign Signature
Location: Moldova

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Dört A Tıp Malzemeleri San. İth. İhr. Tic. Ltd. Şti.

Company Address : Balıkhisar Mah. Köyiçi Serpmeleri No:795/A Akyurt ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product :
- Sterile/ Non-sterile Polypropylene Mesh - Class IIb
- Sterile/ Non-sterile Esu Pencil - Class IIb
- Sterile/ Non-sterile T Drain - Class IIa
- Sterile/ Non-sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile/ Non-sterile PVC Thorax Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Thorax Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Flat Drain (normal/ blue x-ray line) - Class IIa
- Sterile/ Non-sterile PVC Redon Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Redon Drain (blue x-ay line) - Class IIa
- Sterile/ Non-sterile Channel Drain (normal/ blue x-ray line) (Flat/ round) - Class IIa
- Sterile/ Non-sterile Drain Suction Set (Yanquer Set) With vacuum / Without vacuum - Class IIa
- Sterile/ Non-sterile Penrose Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Hemovac Drain Set Single/ Double - Class IIa
- Sterile/ Non-sterile PVC Hemovac Drain Set Single / Double - Class IIa
- Sterile/ Non-sterile Esu Pencil Cleaner - Class Is
- Sterile/ Non-sterile Aspiration Tube - Class Is
- Sterile/ Non-sterile Passive Chest Drainage Bottle 2000ml - Class Is
- Sterile/ Non-sterile Bomb Reservoir - Class Is
- Sterile/ Non-sterile Aspiration Handle (Yanquer Handle) (With vacuum / Without vacuum) - Class IIa

GMDN : 44681, 60300, 35824, 11305, 11301, 35917, 44643

Certificate Number : M.2016.106.7276
Report Number : MD.3334-YB
Initial Assessment Date : 31.07.2012
Registration Date : 05.12.2016
Recertification Assessment Date : 30.11.2020
Reissue Date : 29.04.2021/02
Revision Date /No : -
Expiry Date : 27.05.2024

UDEM APPROVED

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 2068388-1

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG,
P.R. China

Products: Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plates (Grounding Pads)
Replaces Approval, Registration No.: HD 60144580 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 15096008 012

Effective date: 2020-09-11

Expiry date: 2024-05-26

Issue date: 2020-09-11

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 2068388-1

Manufacturer: Intco Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG,
P.R. China

:

No.	Location	Product groups manufactured
/01	Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417 Shanghai P.R. China	Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plates (Grounding Pads)

Report No.: 15096008 012

Effective date: 2020-09-11

Expiry date: 2024-05-26

Issue date: 2020-09-11

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-16
bis / *until* 2023-09-16
Edition 8

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-16

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Leukocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannula
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannula
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line
External Drainage Set
Vent Catheter
Vessel Cannula
Coronary Artery Retraction Clips

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
Products of class Im (with measuring function)

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
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ZLG-BS-236.10.16

SZUTEST

EC CERTIFICATE

AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System

Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1816401

Sertifika Numarası

Manufacturer: *Üretici*
R Vent Medikal Üretim A.Ş.
29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

Product(s): *Ürün(ler)*

(1) Sterile and Non-Sterile Breathing Circuit Systems
(1) Steril ve Steril Olmayan Solunum Devre Sistemleri
(2) Sterile and Non-Sterile Breathing Filters
(2) Steril ve Steril Olmayan Solunum Filtreleri
(3) Sterile and Non-Sterile Catheter Mounts
(3) Steril ve Steril Olmayan Katater Bağlantıları
(4) Non-sterile Masks, BVM (Resuscitator), O_2 & Aerosol Therapy Set
(4) Steril Olmayan Maskeler, BVM (Resusitatör), O_2 & Aeresol Terapi Seti
(5) Sterile Closed Suction System
(5) Steril Kapalı Emiş Sistemi

Reference Report No: *Referans Rapor No*
MM0687-P004-R01, MM0687-P004-R02, MM0687-P005-R01

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.
Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date/*Yayın Tarihi:* 2018-06-13
Revision No./ *Revizyon No.:* 02 Rev./*Rev.*
Revision Date/ *Revizyon Tarihi:* 2020-06-26

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-682

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

Medbar Tıbbi Malzemeler Turizm San. Ve Tic. A.Ş.

Fatih Mah. 1142 Sokak Sarnıç No:35 Gaziemir - İzmir - Turkey

Products: IV Flow Controller, Extension Line, Karman Cannula and Karman Cannula Injector, Arthroscopy Set, Spirometer Filtered Mouthpiece, Skin Marking Set, Mucous Aspirator, Valve Urine Bag, Valve Emesis Bag, Surgical Covers and Drapes, Endoscopy Mouthpiece, Smear Brushes, Amniotic Pouch Perforator, Umbilical Cord Clamp, Sterile Luer Connector Cap (Stopper), Arterial Cannula, Endometrial Suction Curette, Phototherapy Eye Band (Y-Band)

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5746.03
Date of first issue: 13 July 2020
Date of last issue: 11 May 2021
Revision Number: 01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements for Class Im devices and with securing and maintaining sterile conditions in accordance with MDD Annex V for Class Is devices covered by this certificate and found that the quality system meets the applicable requirements in MDD Annex V.

Muhteşem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-682, Revision Number: 01

Concerned medical devices;

Product Name	Types
IV Flow Controller	IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
	Cylindrical IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
Extension Line	Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
	Pressure Resistant Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
Karman Cannula and Karman Cannula Injector	Karman Cannula (No: 3, 4, 5, 6, 7, 8, 9, 10,12)
	Single Valve Manual Vacuum Aspirator Set, Double Valve Manual Vacuum Aspirator Set, Single Valve Manual Vacuum Aspirator, Double Valve Manual Vacuum Aspirator
	Non-Sterile Single Valve Manual Vacuum Aspirator, Non-Sterile Double Valve Manual Vacuum Aspirator
Arthroscopy Set	Y-Tur Set, Y-Tur Set With Pump
Spirometer Filtered Mouthpiece	Small (26mm, 30mm, 33mm)
	Small With Latch (26mm, 30mm, 33mm)
	Big (30mm, 33mm)
	Big With Latch (30mm, 33mm)
Skin Marking Set	Skin Marking Set, Thin Tipped Skin Marking Set
Mucous Aspirator	Mucous Aspirator (15ml, 25ml, 40ml, 100ml)
	Mucous Aspirator With Hose (40ml)
Valve Urine Bag	White, With Discharge
Valve Emesis Bag	Transparent, White
Surgical Covers and Drapes	Microscope Drape, Camera Cover, Cardboard Camera Cover, Telescopic Camera Cover, Circled Camera Cover, Accordion Folded Camera Cover, Probe Cover, Endoscopy Bag, Scopy Cover, C Arm Scopy Cover, Fluoroscopy Cover, Light Handle Cover
Endoscopy Mouthpiece	-
Smear Brushes	Brush, Spatula
Amniotic Pouch Perforator	-
Umbilical Cord Clamp	-
Sterile Luer Connector Cap (Stopper)	-
Arterial Cannula	18G, 20G, 22G
Endometrial Suction Curette	Endometrial Suction Curette, Endometrial Suction Curette With Syringe
Phototherapy Eye Band (Y-Band)	Small, Medium, Large

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

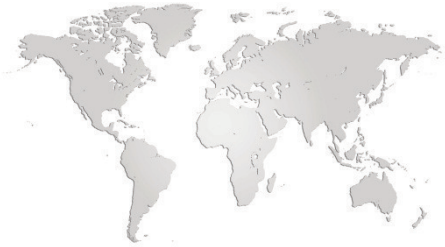
Muhteşem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

IT Dr. Gambert GmbH

Hinter dem Chor 21, 23966 Wismar, Germany

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50403-Z6-00, the decision dated 2018-08-31 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-09-17 to 2023-09-16

Registration No.: 50403-16-07

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50403-16-07

Valid from 2018-09-17 to 2023-09-16

Revision status of the annex: 0 dated 2018-08-31

Devices/device categories included in the certificate:

Class II a:

- Oxygen sensors
- Nitric oxide sensors

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-08-31
Notified Body ID-number: 0124

Ref. Certif. No.

FI-18868

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	**Alternating Pressure Mattress**
Name and address of the applicant Nom et adresse du demandeur	Guangdong Yuehua Medical Instrument Factory Co., Ltd. Rongsheng Science and Technology Zone, Daxue Road, Shantou, Guangdong, China
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant
Name and address of the factory Nom et adresse de l'usine	Same as applicant
Note *When more than one factory, please report on page 2* Note *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	☐ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	230 V a.c.; 50 Hz / 60 Hz; 0,1 A; IP21; Class II
Trademark (if any) Marque de fabrique (si elle existe)	YHMED
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	—
Model / Type Ref. Ref. De type	QDC-303, QDC-300, QDC-301, QDC-500, QDC-501, QDC-800, QDC-303B, QDC-300B, QDC-301B, QDC-500B, QDC-501B, QDC-800B
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire., peuvent être indiqués sur la 2ème page	— ☐ Additional Information on page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1: 2005 + A1: 2012 (Ed.3.1) IEC 60601-1-11: 2010 (Ed.1.0) IEC 60601-1-6: 2010 + A1: 2013 (Ed. 3.1) IEC 62366: 2007 + A1: 2014(Ed. 1.1) National Differences: —
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	GZME150500038201 GZME150500038202 GZME150700068701 GZME150700068702

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

SGS Fimko Ltd.
Särkiniementie 3
FI-00210 Helsinki, Finland

Signature:

Jason Hoo

SGS Fimko Ltd.

Date: 2015-09-10