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 Polypropylene Mesh - Class IIb
- Sterile Esu Pencil - Class IIb
- Sterile T Drain - Class IIa
- Sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile PVC Thorax Drain (blue x-ray line) - Class IIa
- Sterile Silicone Thorax Drain (blue x-ray line) - Class IIa
- Sterile Flat Drain (normal/ blue x-ray line) - Class IIa
- Sterile PVC Redon Drain (blue x-ray line) - Class IIa
- Sterile Silicone Redon Drain (blue x-ay line) - Class IIa
- Sterile Channel Drain (normal/ blue x-ray line) (Flat/ round) - Class IIa
- Sterile Drain Suction Set (Yankuer Set) Vacuum/ Non-Vacuum - Class IIa
- Sterile Penrose Drain (blue x-ray line) - Class IIa
- Sterile Silicone Hemovac Drain Set Single/ Double - Class IIa
- Sterile PVC Hemovac Drain Set Single / Double - Class IIa
- Sterile Esu Pencil Cleaner - Class Is
- Sterile Aspiration Tube - Class Is
- Sterile Passive Chest Drainage Bottle 2000ml - Class Is
- Sterile Bomb Reservoir - Class Is

GMDN : 44681, 60300, 35118, 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 : 26.07.2017
Reissue Date : 24.10.2017/01
Revision Date /No : 09.06.2020/01
Expiry Date : 07.08.2022

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 applied 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 certificate 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 returned upon 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 the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing. Digitally signed by Cojocaru Vera. The validity of the certificate can be checked through www.udem.com.tr.

Digitally signed by Cojocaru Vera
Date: 2021.02.11 09:45:31 EET
Reason: MoldSign Signature
Location: Moldova

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:11 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attestation of Conformity

No. E8A 101233 0008 Rev. 00

Holder of Certificate: **Haining Xinguangyuan Lighting Technology Co.,Ltd.**
No.5 Fenghuang Road,
Qianjiang Industrial
314413 Haining,Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Digitally signed by Cojocaru Vera
Date: 2020.06.08 10:41:11 EEST
Reason: MoldSign Signature
Location: Moldova

Name of Object: **Fluorescent lamps**
Fluorescent lamp

This Attestation of Conformity is issued on a voluntary basis according to the Directive 2014/30/EU relating to electromagnetic compatibility. It confirms that the listed apparatus complies with all essential requirements of the directive and is based on the technical specifications applicable at the time of issuance. It refers only to the particular sample submitted for testing and certification. For details see: www.tuvsud.com/ps-cert

Test report no.: 708882045504-00

Date, 2020-06-08

(Hui Tong)

After preparation of the necessary technical documentation as well as the EU Declaration of conformity the required CE marking can be affixed on the product. That Declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

Attestation of Conformity

No. E8A 101233 0008 Rev. 00

Model(s):

XGYT5-UVA-4W, XGYT5-UVA-6W, XGYT5-UVA-8W, XGYPLS-UVC-11W Ozone,
XGYT5-HO-UVA-15W, XGYT5-UVA-14W, XGYT5-UVA-21W,XGYT5-UVA-28W,
XGYT8-UVA-10W, XGYT8-UVA-15W,XGYT8-UVA-18W, XGYT8-UVA-30W, XGYT8-UVA-36W,
XGYPLS-UVA-5W, XGYPLS-UVA-7W, XGYPLS-UVA-9W,XGYPLS-UVA-11W,
XGYPLS-UVA-13W, XGYPLL-UVA-18W,XGYPLL-UVA-24W, XGYPLL-UVA-36W, XGYT5-BL-4W,
XGYT5-BL-6W, XGYT5-BL-8W,XGYT5-HO-BL-15W, XGYT5-BL-14W, XGYT5-BL-21W,
XGYT5-BL-28W, XGYT8-BL-10W, XGYT8-BL-15W,XGYT8-BL-18W, XGYT8-BL-30W,
XGYT8-BL-36W,XGYT10-BL-20W,XGYT12-BL-20W , XGYPLS-BL-5W, XGYPLS-BL-7W,
XGYPLS-BL-9W, XGYPLS-BL-11W, XGYPLS-BL-13W,XGYPLL-BL-18W,
XGYPLL-BL-24W, XGYPLL-BL-36W,XGYT5-BLB-4W,XGYT5-BLB-6W,
XGYT5-BLB-8W, XGYT5-HO-BLB-15W,
XGYT5-BLB-14W,XGYT5-BLB-21W, XGYT5-BLB-28W, XGYT8-BLB-10W,
XGYT8-BLB-15W, XGYT8-BLB-18W, XGYT8-BLB-30W,XGYT8-BLB-36W, XGYT10-BLB-20W,
XGYT12-BLB-20W, XGYPLS-5W-BLB, XGYPLS-7W-BLB, XGYPLS-9W-BLB,
XGYPLS-11W-BLB, XGYPLS-13W-BLB, XGYPLL-18W-BLB,XGYPLL-24W-BLB,
XGYPLL-36W-BLB, XGYT5-UVC-4W Ozone, XGYT5-UVC-6W Ozone,
XGYT5-UVC-8W Ozone,XGYT5-HO-UVC-15W Ozone,XGYT5-UVC-14W Ozone,
XGYT5-UVC-21W Ozone,XGYT5-UVC-28W Ozone, XGYT8-UVC-10W Ozone,
XGYT8-UVC-15W Ozone,XGYT8-UVC-18W Ozone,XGYT8-UVC-30W Ozone,
XGYT8-UVC-36W Ozone,XGYPLS-UVC-5W Ozone, XGYPLS-UVC-7W Ozone,
XGYPLS-UVC-9W Ozone, XGYPLS-UVC-11W Ozone, XGYPLS-UVC-13W Ozone,
XGYPLL-UVC-18W Ozone, XGYPLL-UVC-24W Ozone, XGYPLL-UVC-36W Ozone,
XGYT5-UVC-4W No Ozone, XGYT5-UVC-6W No Ozone,XGYT5-UVC-8W No Ozone,
XGYT5-HO-UVC-15W No Ozone, XGYT5-UVC-14W No Ozone,
XGYT5-UVC-21W No Ozone,XGYT5-UVC-28W No Ozone, XGYT8-UVC-10W No Ozone,
XGYT8-UVC-15W No Ozone,XGYT8-UVC-18W No Ozone, XGYT8-UVC-30W No Ozone,
XGYT8-UVC-36W No Ozone,XGYPLS-UVC-5W No Ozone, XGYPLS-UVC-7W No Ozone,
XGYPLS-UVC-9W No Ozone, XGYPLS-UVC-11W No Ozone, XGYPLS-UVC-13W No Ozone,
XGYPLL-UVC-18W No Ozone, XGYPLL-UVC-24W No Ozone, XGYPLL-UVC-36W No Ozone

Description of Object:

Rated voltage: AC 220-240V
Rated frequency: 50/60Hz
Rated power: See model list

Model list	Rated power
XGYT5-UVA-4W, XGYT5-BL-4W, XGYT5-BLB-4W, XGYT5-UVC-4W Ozone, XGYT5-UVC-4W No Ozone	4W
XGYPLS-UVA-5W, XGYPLS-BL-5W, XGYPLS-5W-BLB, XGYPLS-UVC-5W Ozone, XGYPLS-UVC-5W No Ozone	5W
XGYT5-UVA-6W, XGYT5-BL-6W, XGYT5-BLB-6W, XGYT5-UVC-6W Ozone, XGYT5-UVC-6W No Ozone	6W
XGYPLS-UVA-7W, XGYPLS-BL-7W, XGYPLS-7W-BLB, XGYPLS-UVC-7W Ozone, XGYPLS-UVC-7W No Ozone	7W
XGYT5-UVA-8W, XGYT5-BL-8W, XGYT5-BLB-8W, XGYT5-UVC-8W Ozone, XGYT5-UVC-8W No Ozone	8W
XGYPLS-UVA-9W, XGYPLS-BL-9W, XGYPLS-9W-BLB, XGYPLS-UVC-9W Ozone, XGYPLS-UVC-9W No Ozone	9W
XGYT8-UVA-10W, XGYT8-BL-10W, XGYT8-BLB-10W, XGYT8-UVC-10W Ozone, XGYT8-UVC-10W No Ozone	10W
XGYPLS-UVA-11W, XGYPLS-BL-11W, XGYPLS-11W-BLB, XGYPLS-UVC-11W Ozone, XGYPLS-UVC-11W No Ozone, XGYPLS-UVC-11W Ozone	11W
XGYPLS-UVA-13W, XGYPLS-BL-13W, XGYPLS-13W-BLB, XGYPLS-UVC-13W Ozone, XGYPLS-UVC-13W No Ozone	13W

After preparation of the necessary technical documentation as well as the EU Declaration of conformity the required CE marking can be affixed on the product. That Declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attestation of Conformity

No. E8A 101233 0008 Rev. 00

Model list	Rated power
XGYT5-UVA-14W, XGYT5-BL-14W, XGYT5-BLB-14W, XGYT5-UVC-14W Ozone, XGYT5-UVC-14W No Ozone	14W
XGYT5-HO-UVA-15W, XGYT8-UVA-15W, XGYT5-HO-BL-15W, XGYT8-BL-15W, XGYT5-HO-BLB-15W, XGYT8-BLB-15W, XGYT5-HO-UVC-15W Ozone, XGYT8-UVC-15W Ozone, XGYT5-HO-UVC-15W No Ozone, XGYT8-UVC-15W No Ozone	15W
XGYT8-UVA-18W, XGYPLL-UVA-18W, XGYT8-BL-18W, XGYPLL-BL-18W, XGYT8-BLB-18W, XGYPLL-18W-BLB, XGYT8-UVC-18W Ozone, XGYPLL-UVC-18W Ozone, XGYT8-UVC-18W No Ozone, XGYPLL-UVC-18W No Ozone	18W
XGYT10-BL-20W, XGYT12-BL-20W, XGYT10-BLB-20W, XGYT12-BLB-20W	20W
XGYT5-UVA-21W, XGYT5-BL-21W, XGYT5-BLB-21W, XGYT5-UVC-21W Ozone, XGYT5-UVC-21W No Ozone	21W
XGYPLL-UVA-24W, XGYPLL-BL-24W, XGYPLL-24W-BLB, XGYPLL-UVC-24W Ozone, XGYPLL-UVC-24W No Ozone	24W
XGYT5-UVA-28W, XGYT5-BL-28W, XGYT5-BLB-28W, XGYT5-UVC-28W Ozone, XGYT5-UVC-28W No Ozone	28W
XGYT8-UVA-30W, XGYT8-BL-30W, XGYT8-BLB-30W, XGYT8-UVC-30W Ozone, XGYT8-UVC-30W No Ozone	30W
XGYT8-UVA-36W, XGYPLL-UVA-36W, XGYT8-BL-36W, XGYPLL-BL-36W, XGYT8-BLB-36W, XGYPLL-36W-BLB, XGYT8-UVC-36W Ozone, XGYPLL-UVC-36W Ozone, XGYT8-UVC-36W No Ozone, XGYPLL-UVC-36W No Ozone	36W

Tested according to:

EN 55015:2013
EN 55015:2013/A1:2015
EN 61547:2009
EN 61000-3-2:2014
EN 61000-3-3:2013

After preparation of the necessary technical documentation as well as the EU Declaration of conformity the required CE marking can be affixed on the product. That Declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

BSS
Better Signal Solution

BSS MEDICAL SUPPLY CO., LIMITED

Document Number : CE-DC-001 Version: A/1

EC Declaration of Conformity

Manufacturer:

BSS MEDICAL SUPPLY CO., LIMITED
No.18, Shabian Road, Torch Hi-tech Industry Zone,
Zhonggshan, China.
info@bssmedical.com

whose single Authorized Representative:

Wellkang Ltd.
Suite B, 29 Harley Street
LONDON, W1G 9QR,U.K.
info@bssmedical.com

We, the manufacturer, herewith declare that the products

Disposable ECG electrode

GMDN Code:11425

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

Conformity assessment procedure: Annex VII of Directive 93/43/EEC

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: BSS MEDICAL SUPPLY CO., LIMITED
Address: No.18, Shabian Road Torch Hi-tech Industry Zone, Zhongshan, China.

ZHONGSHAN2018/01/01
Place , date

Legally binding signature, Function

18-BEY-01 Adult Electrode LOT: 04192018

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.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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 III
Products of class III

Vent Catheter
Atrial Cannula
Vessel Cannula with / without check valve

Anmerkung: Für das Inverkehrbringen der in diesem Zertifikat genannten Klasse III Produkte wird eine gültige EG Auslegungsprüfbescheinigung gemäß MDD Anhang II (4) gefordert.
Note: *For the placing on the market of Class III devices covered by this certificate, a valid EC design-examination certificate according to MDD Annex II (4) is required.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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*

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ANLAGE / *ANNEX*

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

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Lekocyte 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.* 3521 8285

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ANLAGE / *ANNEX*

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

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannulae
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannulae
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.* 3521 8285

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Edition 12

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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 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

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
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Edition 12

Zertifizierungsstelle für Medizinprodukte
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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.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

M2.98

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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*

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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.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
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Essen, 2018-08-03

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

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www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Anlage 1, Blatt 7 von 7
Annex 1, page 7 of 7

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.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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

Certificate of Registration

This is to certify that the Quality Management System of

BSS MEDICAL SUPPLY CO., LIMITED

Organization Code : 09461571-8
Operation Address : Unit B, 3F, Building 3, 1 of No.18, Shabian Road, Torch Hi-Tech Industry Zone, Zhongshan City, Guangdong Province, China
Registered Address : Unit B, 3F, Building 3, 1 of No.18, Shabian Road, Torch Hi-Tech Industry Zone, Zhongshan City, Guangdong Province, China

applicable to

Manufacture of disposable ECG electrode,Grounding Plates, ECG Paper, Alcohol Swabs

has been assessed and registered by NQA against the provisions of

ISO 13485: 2003

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number 42377

Date: 08 August 2016
Valid Until: 31 March 2019
EAC Code: 19

UKAS MANAGEMENT SYSTEMS
015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

ROYALCERT INTERNATIONAL REGISTRARS

SERTİFİKA

Sertifika No	**: 00108/DÖR13A**
Belgelendirme Tarihi	**: 20.01.2010**
Yeniden Belgelendirme Karar Tarihi	**: 31.12.2018**
Yayın Tarihi	**: 11.01.2020**
Geçerlilik Tarihi	**: 19.01.2021**
Revizyon Tarihi/No	**: 31.12.2018 / 01**

RoyalCert Belgelendirme, aşağıda bilgileri verilen kuruluşun yönetim sisteminin yine aşağıda detayları verilen yönetim standardının gereklerine uygunluğunu değerlendirmiş olup, ilgili standart şartlarına uygun olduğunu onaylar.

ISO 13485:2016

DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. STİ.

Balıkhisar Mahallesi Köyiçi Serpmeleri No:795/A Akyurt / ANKARA, TÜRKİYE

Kapsam: *Sterilizasyon Rulosu ve Torbaları, Kendinden Yapışkanlı Sterilizasyon Zarfları, Bowie-Dick Testi Paketleri, İndikatör Kartları (H2O2 (Plasma), Formaldehit İndikatör Kartları, Etilen Oksit İndikatör Kartları, Kuru Hava İndikatör Kartları, Sınıf 4 İndikatör Kartları, Sınıf 5 İndikatör Kartları, Sınıf 6 İndikatör Kartları), Sınıf 5 İntegratör, Rapid Buhar Biyolojik İndikatörü, Uzun Süreli Buhar Biyolojik İndikatörü, Etilen Oksit Biyolojik İndikatörü, H2O2 (Plasma) Biyolojik İndikatörü, Helix Küme Testi, Pcd Küme Testi, Etilen Oksit Yük Kontrol Testi, Otoklav Bantları (Buhar, Etilen Oksit, Plasma, Formaldehite), Koter Kalemleri, Koter Zımparası, Wrap ve Krep Kağıtları, Vücüt-Yara Atık Sıvıları için Drenaj Sistemleri (Kateterler, Toplama Şişeleri), Polypropylene Mesh, Steril Konteynır Sistemleri, Konteynır Etiketi, Konteynır Kilidi, Konteynır Filtresi, İndikatörlü Dokümantasyon Etiketleri, İndikatörlü Rulo Barkod Etiketleri; Yıkayıcı Dezenfektörler, Ultrasonik Cihazlar Ve Cerrahi Aletlerin Yıkama Kontrol Testleri (Protest, Hemotest, Washertest, Cannulacontrol Test, Sonicontrol Test) , İkili Biyolojik İndikatör Test Paketi (Biyolojik Indikatör - Class 5 Entegratör), İkili Yük Kontrol Test Paketi (Class 5 Entegratör ve PCD içi Class 6 İndikatör), Üçlü Biyolojik İndikatör Test Paketi (Biyolojik İndikatör, Class 5 Entegratör ve PCD İçi Class 6 İndikatör), Steril ve Non Steril Ağız Bakım Seti(Ağız Bakım Çubuğu, Gargara Solüsyonu, Jel) Üretimi, Tasarımı, Montajı, Paketlenmesi, Pazarlanması ve Satışı, Tek Kullanımlık Tıbbi Malzemelerin Paketlenmesi.*

Genel Müdür

ROYALCERT INTERNATIONAL REGISTRARS
ROYALCERT

RoyalCert

FSC

Bu sertifika, belgeli kuruluş gözetim denetimleri şartlarına ve RoyalCert'in prosedürlerine uyduğu sürece geçerlidir.
Orjinal belgede hologram etiket bulunur .Belgelendirme periyodu 3 yıldır.
Sertifikanın durumu www.royalcert.com adresinden ayrıca üzerinde kare kod bulunan sertifikaların geçerliliği de TÜRKAK BDS no. ile TBDS.turkak.org.tr üzerinden doğrulanabilir.

RoyalCert Belgelendirme ve Gözetim Hizmetleri A.Ş
Kar Plaza, E Blok, Kat:13, 34752, Ataşehir
İstanbul - Türkiye
T: +90 216 688 09 10

ROYALCERT INTERNATIONAL REGISTRARS

CERTIFICATE

Certification No	**: 00108/DÖR13A**
Initial Certification Date	**: 20.01.2010**
Recertification Date	**: 31.12.2018**
Issue Date	**: 11.01.2020**
Expiration Date	**: 19.01.2021**
Revision Date / No	**: 31.12.2018 / 01**

RoyalCert International Registrars, certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

ISO 13485:2016

DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. STİ.

Balıkhisar Mahallesi Köyiçi Serpmeleri No:795/A Akyurt / ANKARA, TÜRKİYE

Scope: *Production, Design, Assembly and Packaging of Sterilization Reels and bags, Self Adhesive Sterilization Pouches, Bowie-Dick Test Packages, Indicator Strips (H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Class 4 Indicator Strip, Class 5 Indicator Strip, Class 6 Indicator Strip), Class 5 Integrator, Rapid Steam Biological Indicator, Longtime Steam Biological Indicator, Ethylene Oxide Biological Indicator, H2O2 (Plasma) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide Load Control test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquid Wastes (Catheters, Storage Bottles), Polypropylene Mesh, Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator, Washer Disinfectors, Ultrasonic Devices and Washing Control Tests of Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Cannula Control Test, Sonicontrol Test), Double Biological Indicator Test Package (Biological Indicator- Class 5 Integrator), Double Load Control Test Package (Class 5 Integrator and Inner PCD Class 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Class 5 Integrator and Inner PCD Class 6 Indicator) and Packaging,of Disposable Medical Products*

General Manager

ROYALCERT INTERNATIONAL REGISTRARS ROYALCERT

RoyalCert

FSC

This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits.
The original certificate contains a security hologram.
Certification period is 3 years. Verifiable at: www.royalcert.com

RoyalCert International Registrars GmbH
Kölner Strasse 44, D-60327
Frankfurt am Main Germany
T: +49 698 609 25 69 | F: +49 691 729 73 00

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

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

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält.
Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.
This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung, Sterilisation und Vertrieb von medizinischen Einmalartikeln.
Entwicklung, Herstellung und Vertrieb von medizinischen Geräten und deren Zubehör.

Design, Manufacturing, Sterilization and Distribution of Disposable Medical Devices.
Design, Manufacturing and Distribution of Medical Equipments and all their Accessories.

Reg.-Nr. / *Reg.-No.* 04 221 980886
Bericht Nr. / *Report No.* 3521 8284

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 6

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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*

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-05-01