EC-Declaration of Conformity

Manufacturer:

Name	:	METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
Address	:	İvedik O. S. B. Ağaç İşleri Sanayi Sitesi 1354 Cad. 1358 Sok. No:9 06378 Yenimahalle - Ankara \ Turkey
Tel	:	+ 90 312 387 12 46 (pbx)
Fax	:	+ 90 312 387 12 51
E-mail	:	metko@metkoltd.com
Web	:	www.metkoltd.com

Authorized European Representative:

Name	:	Medset Medizintechnik GmbH
Address	:	Curslacker Neuer Deich 66 D-21029 Hamburg \ Germany
Tel	:	0049 40 725 822- 0
Fax:		0049 40 725 822-11
E-mail	:	info@medset.com
Web	:	www.medset.com

Product: Electrosurgery Cables & Accessories

Electrosurgery Bipolar Cables, (GMDN Code: 35041)
Electrosurgery Monopolar Cables, (GMDN Code: 61876)
Electrosurgery Dispersive Cables, (GMDN Code: 35041)
Electrosurgery Bipolar Adaptors, (GMDN Code: 35041)
Electrosurgery Disposable Grounding Plates, (GMDN Code: 11500)
Electrosurgery Reusable Grounding Pads, (GMDN Code: 42551)
Electrosurgery Reusable Connection Cable for Universal Patient Return Electrodes, (GMDN Code: 35041)
Tip Clean Sponge, (GMDN Code: 35043)

Reference Numbers:
ESU-BP/XXY Series, ESU-BP/CONA, ESU-BP/CONAL, ESU-BP/OWE, ESU-BP/FWE, ESU-BP/BWE, ESU-BP/LWE, ESU-BP/GYR, ESU-BP/GYRL (XX variables: AA to ZZ; Y variables: -, L, T, TL)
ESU-MP/XXY Series (XX variables: AA to ZZ; Y variables: -, L)
RDC-XXY Series (X variables: A to Z; Y variables: 3, 5, 3A and 5A)
ESU-ADP/XX Series (XX variables: 01 to 10)
RGPC-XX Series (XX variables: 00 to 99)
FMT-MX, FMT-BX and FMT-CXX Series (X variable: A, P), (XX variable: BA, BP, MA, and MP)
FMT-RGPX Series (X variable: B, M)
FMT-MDX (X variables: 1 to 9)
TSC 01

Classification: Class I Medical Device, Annex IX Rule 1
Conformity Assessment Procedure: Annex VII

We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.

Standards:

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN IEC 60601-2-2:2018	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 17664:2017	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

Date of issue: 10.02.2020

Signature:

Digitally signed by Cojocaru Vera
Date: 2020.07.08 09:38:21 EEST
Reason: MoldSign Signature
Location: Moldova

Name: Filiz ERSOY
Position: Company Manager

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

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

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

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

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-075

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

METKO MEDİKAL VE TIBBİ CİHAZLAR DIŞ TİCARET LİMİTED ŞİRKETİ

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378 Yenimahalle, Ankara, Turkey

Products: Sterile and Non-Sterile Pulse Oximetry (SpO2) Sensors and Medical Temperature Probes, Sterile Disposable Pressure Transducer

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.3393.10
Date of first issue:	23 December 2010
Date of last issue:	16 April 2019
Revision Number:	09
Expiry Date:	20 November 2020

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

16 April 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
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 Declaration of Conformity

Manufacturer:

Jinhua Huacheng Medical Appliance Co.,Ltd.
No.186 Qingyu Road, Jindong Industrial Park,
Jinhua City, 321000 Zhejiang, China

whose single Authorized Representative:

Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Disposable Surgical Active Electrodes (Electrosurgical Pencils)

Hand control Model：HC-EP1-A/70，HC-EP1-B，HC-EP1-C，HC-EP1-A/100，
HC-EP1-A/120，HC-EP1-A/140

GMDN-Code: **[44681]**

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

The medical device has been assigned to class IIb by rule 9 according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II.3 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60131017 0001
Issue date: 2018-09-18
Expiry date: 2023-09-17

following the procedure relating to the EC Declaration of Conformity set out in Annex II.3 of Directive 93/42/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

Jinhua Huacheng Medical Appliance Co.,Ltd.
No.186 Qingyu Road, Jindong Industrial Park, Jinhua City, 321000 Zhejiang, China

Jinhua, China 2018.09.06

Place, date

Legally binding signature, Function

金华市华诚医疗器械有限公司
Jinhua Huacheng Medical Appliance Co.,Ltd.

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*

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

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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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
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

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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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 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

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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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

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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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 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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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
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

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.* 3521 8285

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

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ZLG-BS-236.10.16

ÇİFTÇİLERBİRLİK
KAĞITÇILIK HİJYENİK ÜRÜNLER ve YAĞ SAN. A.Ş.

Orta Mahallesi ,Marifet Sokak, No: 15/1A Kartal / İstanbul-Turkey
Tel: +90 (216) 451 00 00 Fax: +90 (216) 452 00 00
info@cihangroup.com - www.cihangroup.com

CE

EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

We,

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ
Herewith declare that Adult Diaper, Underpad and Pull Up Adult Pants for medical use

FLEXI LIFE (MEDIUM, LARGE, X LARGE)
FLEXI LIFE PLUS (MEDIUM, LARGE, X LARGE)

are produced in our manufacturing place,

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ
3.Organize Sanayi Bölgesi, 10.Yol , No: 79
Söğütlü Sakarya Turkey

according to harmonize standards,

TS EN ISO 13485:2016 –TS EN ISO 9001:2015 – TS EN ISO 22716:2007 (GMP)

and according to

Medical Devices Directive 93/42/EEC Annex VII Declaration of Conformity Product Classification: Class 1 (93/42/EEC Annex IX, Rule 1)

Issued Date : 28.10.2019
ISTANBUL

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ

3. Organize Sanayi Bölgesi 10. Yol No:79 Söğütlü / Sakarya / TÜRKİYE

Tek Kullanımlık Kullan-At Ürünleri (Streç Film, Alüminyum Folyo, Buzdolabı Poşeti, Pişirme Kağıdı, Hidrofil Pamuk, Pamuklu Çubuk, Plastik Tabak, Kaşık, Çatal, Bardak, Çöp Şiş, Mum, Naftalin, Çöp Poşeti, Alüminyum Kaplar, Lavabo Açıcı, Temizlik Bezi, Pipet, Yatak Koruyucu Örtü,Kaydırmaz Bantlı Yatak Koruyucu Örtü, Hasta Bezi, Emici Külot Hasta bezi, Bebek Bezi, Alt Değiştirme Örtüsü, Hayvan Alıştırma Pedi, Islak Havlu, Tuvalet Kağıdı, Jumbo Tuvalet Kağıdı, Havlu Kağıt,Islak Mendil, Mendil,Peçete, Muayene Masa Örtüsü, Dispenser Peçete, Dispenser Havlu, Hareketli Havlu, İçten Çekmeli Tuvalet Kağıdı, İçten Çekmeli Havlu, Klozet Kapak Örtüsü, Yara ve Cilt Temizleme Havlusu, Saç Yıkama Bonesi, Polyester ve Viskon Kumaştan Temizlik Bezi, Tekstil Yüzeyli Hasta Bezi, Hasta Lifi, Vücut Temizleme Havlusu, Vücut Yıkama Kesesi, Perine Temizleme Havlusu) Üretimi ve Satışı

Production and Sales of Disposable Products (Stretch Film, Aluminum Foil, Freezer Bag, Baking Paper, Hydrophilic Cotton, Cotton Stick, Plastic Plate-Spoon-Fork-Glass ,Cup, Garbage Skewers, Candle, Naphthalene, Garbage Bag, Aluminum Containers, Sink Opener, Cleaning Cloth, Pipette, Underpad, Non-Slip Underpad, Adult Diaper, Pull Up Adult Diaper, Baby Diaper, Baby Diaper Changing Mat, Dog Training Pad, Wet Towel,Toilet Paper, Jumbo Toilet Paper, Kitchen Towel, Wet Wipes, Handkerchief, Napkin, Examination Table Cloth, Dispenser Napkin, Dispenser Towel, Emotion Towel, Centerfeed Toilet Paper, Centerfeed Towel, Toilet Seat Cover Cloth, Wound and Skin Cleaning Towel, Hair Wash Cap, Polyester and Viscose Cleaning Cloth, Textile Surface Adult Diaper, Hygenic Fiber, Body Cleaning Towel, Perineal Area Cleaning Towel

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu Medikal Cihaz Yönetim Sisteminin
is audited by TCS Certification and applied Medical Devices Management System meet the requirements of

ISO 13485:2016

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

Sertifika No / *Certificate No:* **MDM-00 90 180661-TR**

Sertifika İlk Yayın Tarihi / *Certificate Date* 28.09.2018

Sertifika Son Basım Tarihi / *Certificate Last Issue Date* 17.10.2019

Mevcut Belgelendirmenin Geçerlilik Periyodu / *Validity Date of Current Certification Period* 28.09.2018-28.09-2021

INSPECTION PRODUCT TRAINING TCS SYSTEM DEPARTMENT

SERTİFİKA GEÇERLİLİK TARİHİ : 28.09.2021

ONAY
APPROVAL

Kocasinan Cad. Yanardağ Sk. No: 9/11 Küçükbakkalköy Ataşehir / İstanbul
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Jinhua Huacheng Medical Appliance Co., Ltd.
No. 186 Qingyu Road
Jindong Industrial Park
Jinhua City
321000 Zhejiang
China

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

Design, Development, Manufacture and Distribution of Disposable Electrosurgical Pencils, Disposable Neutral Electrodes, Physiotherapy Electrodes, Disposable ECG Electrodes, Disposable Skin Staplers

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-09-18
Certificate Registration No.:	SX 60131018 0001
An audit was performed. Report No.:	15062970 008
This Certificate is valid until:	2021-09-17

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-09-05

S. Liu

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

CERTIFICATE

TELKAR ÇEVRE SAĞLIK ENDÜSTRİYEL PLASTİK SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fetih Mh. Libadiye Cad. Sarıkamış Sk. No:52 Ataşehir / İstanbul / TÜRKİYE

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu Kalite Yönetim Sisteminin
is audited by TCS Certification and applied Quality Management System meet the requirements of

ISO 9001:2015

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

Atık Kutuları, Kesici ve Delici Atık Kutusu, Enfekte Atık Kutusu, Konteyner Tehlikeli Atık Kutuları, Tıbbı Atık Kutuları, Her Türlü Atık Torbaları, Her Türlü Poşet ve Torbalar, Endüstriyel Hijyen Ekipman ve Malzemeleri Sağlık Ürünleri İmalatı Pazarlaması ve Satışı

Manufacturing Marketing and Sales of Waste Boxes, Cutting and Drilling Waste Boxes, Infected Waste, Hazardous Waste Container Boxes, Medical Waste Bins, All Kinds of Waste Bags, Bag and All Kinds of Bags, Industrial Hygiene Equipment & Supplies, Health Care

Sertifika No / *Certificate No:* **QM-00 90 180662-TR**

Sertifika İlk Yayın Tarihi / *Certificate Date* 28.09.2018

Sertifika Son Basım Tarihi / *Certificate Last Issue Date* 28.09.2018

Mevcut Belgelendirmenin Geçerlilik Periyodu / *Validity Date of Current Certification Period* 28.09.2018-28.09.2021

SERTİFİKA GEÇERLİLİK TARİHİ : 28.09.2019

ONAY
APPROVAL

FRM.S.74_REV05

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