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

Digitally signed by Cojocaru Vera
Date: 2023.03.31 16:33:42 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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

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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
External Drainage Set
Vent Catheter
Vessel Cannula
Coronary Artery Retraction Clips

Bericht Nr. / *Report No.* 3529 1130

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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

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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.* 3529 1130

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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*
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EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60143699 0001

Report No.: 15059498 012

Manufacturer:
Jiangsu Brightness Medical Devices
Co., Ltd.
The 3rd floor of Building 3, Building 1
& Building 5-3, No.66, Hehuan Road
Zhonglou Economic Development Area
Changzhou
213013 Jiangsu
P.R. China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60129487 0001

Expiry Date: 2023-06-04

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.

Effective Date: 2020-04-26

Date: 2020-04-26

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60143699 0001
Report No.: 15059498 012

Manufacturer:

Jiangsu Brightness Medical Devices Co., Ltd.
The 3rd floor of Building 3, Building 1 & Building 5-3, No.66, Hehuan Road
Zhonglou Economic Development Area
Changzhou
213013 Jiangsu
P.R. China

Products:

- Non-vascular Stents
- Disposable Endoscopic Ligating Loops
- Disposable Clip Appliers
- Disposable Veress Needles
- Disposable Endoscopic Retrieval Bags
- Disposable Suction and Irrigation Tubes
- Disposable Trocars
- Disposable Endoscopic Dissectors
- Skin Staplers and Removers
- Disposable Circular Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Stapler and Reloads
- Disposable Linear Cutter Staplers and Reloads
- Disposable Curved Cutter Staplers
- Disposable Endocutters & Disposable Endocutter Reloads

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2020-04-26

CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.
Company Address	: Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELI / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Ready To Use Wound Dressing (Nonwoven Polyurethane) - Class I Sterile Eye Pad - Class Is Sterile Haemostatic Pressure Band - Class Is Steril Catherer Fixation Band - Class Is - Nonwoven, Transparent - Polyurethane Nonwoven With Pad - Transparent With Pad - Polyurethane With Pad
GMDN	: 34864, 11661
Certificate Number	: M.2018.106.9658
Report Number	: MD.3508.YB
Initial Assessment Date	: 19.01.2016
Registration Date	: 10.05.2018
Recertification Assessment Date	: 05.12.2018
Reissue Date / No	: 27.02.2019/01
Revision Date /No	: -
Expiry Date	: 07.02.2024

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

UDEM hereby declares that the requirements of Annex V 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 audits, defined by Annex V, section 4 of the aforementioned directive. 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 dev,ce 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 expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

CE 2292

Addrres: 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

CERTIFICATE

Certification No	**: 00108/DÖR13A**
Initial Certification Date	**: 20.01.2010**
Recertification Date	: 07.01.2022
Issue Date	**: 07.01.2022**
Expiration Date	**: 19.01.2023**
Revision Date / No	**: 31.12.2018 / 01**

RoyalCert, 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 SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Balıkhisar Mahallesi, Köy İçi Serpmeleri, No:795/A, Akyurt, Ankara, TURKEY

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, Type 4 Indicator Strip, Type 5 Indicator Strip, Type 6 Indicator Strip), Type 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- Type 5 Integrator), Double Load Control Test Package (Type 5 Integrator and Inner PCD Type 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicator) and Packaging,of Disposable Medical Products*

General Manager

ROYALCERT INTERNATIONAL REGISTRARS
ROYALCERT

This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveilance audits.
The original certificate contains a security hologram.
Certification period is 3 years Verifiable at; www.royalcert.com
This certification can be verified on TÜRKAK BDS no. and TBDS.turkak.org.tr

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

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