DECLERATION OF CONFORMITY

EC Decleration of Conformity:	MEDiCAL DEViCES DiRECTiVES (93/42/EEC) APPENDiX-Vii
Manufacturer:	HEGELi ORTOPEDiK ÜRÜNLER SAN. TiC. LTD. ŞTi
Manufacturer's address:	Cihangir Mah. Şehit Piyade Er Yavuz Bahar Sok. No:4 Mirabbo Sanayi Sitesi D: Blok Kat:3 Ambarlı – Avcılar – istanbul – Turkey
Device/s:	ORTHOPEDiC SUPPORT PRODUCTS
Description:	MEDiCAL DEViCE(S) THAT SUPPORT(S) THE HUMAN BODY EXTERNALLY.
EC Product Class:	CLASS 1

MEDiCAL DEViCES DiRECTiVES (93/42/EEC) - APPENDiX Vii

STANDARDS:

EN 980: 2008:	Graphical symbols for use in the labelling of medical devices.
EN ISO 14971: 2012	Medical devices. Application of risk management to medical devices
EN 1041: 2008 + A1: 2013	information supplied by the manufacturer of medical devices.
EN 14971: 2004:	The risk analysis for medical devices.

Digitally signed by Cojocaru Vladimir
Date: 2020.01.20 03:35:26 EET
Reason: MoldSign Signature
Location: Moldova

HEGELİ ORTOPEDİK ÜRÜNLER SAN. ve TİC.LTD.ŞTİ.
Cihangir Mah. Şehit Piyade Er Yavuz Bahar Sok.
Mirabbo San. Sit. No:4-D Blok K:2
Ambarlı - Avcılar / İSTANBUL
Tel: 0212 428 50 07 - 08 Fax: 0212 428 51 07
Avcılar V.D.: 461 038 4081 Tic.Sic. No: 582033

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE

号码 No. 173100B0/06860

兹证明：所附登记号HD 60118145 0001 EC证书的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of EC CERTIFICATE Registration No. HD 60118145 0001 is in conformity with the original.

№14306

ASTER ÜZERINE EKLENMİŞTİR. TEK BAŞINA KULLANILAMAZ

ASLININ AYNIDIR.

China Council for the Promotion of International Trade

授权签字：

Authorized Signature : *Chen Hong*

日期：2017 年04月19日

(Date: APR. 19, 2017)

OFFICIAL TRANSLATION OFFICE
SKY TERCÜME
Pendik : 390 29 10
İmes : 364 20 19
Tuzla : 395 76 30
Deri OSB: 394 26 02
SKY

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60118145 0001

Report No.: 15049299 009

Manufacturer: Shanghai HBM Healthcares, Inc.
902-904, No.255 New
Golden Bridge Road,
201206 Shanghai
China

#14306

Products:
- Latex Condoms
- Surgical Gloves

Replaces Approval, Registration No.: HD 60076051 0001

ASLININ AYNIDIR.

Expiry Date: 2022-03-30

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.

Notified Body

Effective Date: 2017-03-31

İSTEK ÜZERİNE ÇOĞALTILMIŞTIR.
TEK BAŞINA KULLANILAMAZ

Date: 2017-03-31

X. Ren

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.

OFFICIAL TRANSLATION OFFICE
TÜV Rheinland LGA Products GmbH
SKY
TERCÜME
Pendik: 390 29 10
İmes: 384 20 19
Tuzla: 395 75 90
Deri OSB: 394 26 02
SKY

THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
(Turkish Medicines and Medical Devices Agency)

Date of issue : 9 June 2017

TO WHOM IT MAY CONCERN

HEALTH CERTIFICATE
Free Sales Certificate

Medical devices, which are in the scope of Medical Devices Directives, listed additional page(s), produced by the manufacturer called "YASİR TEKER MEDOFFİCE TIBBİ MALZEME TEKSTİL KİMYA İTHALAT İHRACAT SANAYİ VE TİCARET (MERİÇ MAH. 5746/10 SK. No:16/1 BORNOVA /İZMİR Bornova / İzmir / TÜRKİYE)" is freely sold in Turkey and European Union and exported to other countries.

This certificate expiresafter 36 months from the date of issue.

Sincerely Yours

Yalçın SOYSAL, MD.
Head of Medical Device Department

EC Certificate

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

Registration No.: HD 60134523 0001

Report No.: 17056756 003

Manufacturer:
Life Medical Equipment
(Guangzhou) Co., Ltd.
5th floor, 13th building Julong
industrial Zone
827 Xicha Road, Baiyun district
Guangzhou
510407 Guangdong
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60120141 0001

Expiry Date: 2021-06-29

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: 2019-01-16

Date: 2019-01-16

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134523 0001
Report No.: 17056756 003

Manufacturer:
Life Medical Equipment
(Guangzhou) Co., Ltd.
5th floor, 13th building Julong
industrial Zone
827 Xicha Road, Baiyun district
Guangzhou
510407 Guangdong
China

Products:

- Arterial Venous (A.V.) Cannulas
- Tracheobronchial Tube Kits
- Enteral Feeding Tubes
- Enteral Feeding Sets
- Disinfection Caps

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Needleless Adapters
- Stopcocks
- IV Infusion Sets
- Extension Sets
- Decompression Pads
- Heparin Caps
- Urine Bags

Date: 2019-01-16

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60136001 0001

Report No.: 15065241 009

Manufacturer:

Huaian Angel Medical Instruments
Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60101257 0001

Expiry Date: 2024-01-26

The Notified Body 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, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-01-27

Date: 2019-01-17

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60136001 0001
Report No.: 15065241 009

Manufacturer:
Huaian Angel Medical instruments Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products:

- Disposable Suture Needles
- Disposable Surgical Blades & Scalpels with Plastic Handle
- Sterile Blood Lancets
- Surgical Instruments Kits

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Urinary Drainage Bags
- Disposable Umbilical Cord-Clamps

Date: 2019-01-17

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

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

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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 081232 0010 Rev. 01

Manufacturer:

AnHui Hongyu Wuzhou Medical Manufacturer Co.,Ltd.
No.2 Guanyin Road
Economic Development Zone
Taihu County
246400 Anqing, Anhui
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Insulin Syringes for Single Use, Insulin Pen-injectors for Medical Use, Transfusion Sets for Single Use, Infusion Sets for Single Use(Gravity Feed), Burette-type Infusion Sets for Single Use, Intravenous Needles for Single Use, Blood Collection Needles for Single Use, Sterile Dental Injection Needles for Single Use, Disposable Precision Flow Regulator, Insulin Pen Needles for Single Use, Blood Collection Sets for Single Use, Sterile Safety Hypodermic Needles for Single Use, Safety Blood Collection Sets for Single Use, Safety Blood Collection Needles for Single Use

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

Report No.: SH1873508

Valid from: 2018-08-01
Valid until: 2022-08-19

Date, 2018-08-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 081232 0010 Rev. 01

Facility(ies):

AnHui Hongyu Wuzhou Medical Manufacturer Co.,Ltd.
No.2 Guanyin Road, Economic Development Zone, Taihu County,
246400 Anqing, Anhui, PEOPLE'S REPUBLIC OF CHINA

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

TÜV®

EC Certificate

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

Registration No.: HD 60139711 0001

Report No.: 17047213 009

Manufacturer:

SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60101918 0001

Expiry Date: 2024-05-27

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: 2019-08-05

Date: 2019-08-05

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139711 0001
Report No.: 17047213 009

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Products:

- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Angiographic Syringes
- Hemodialysis Catheterization Kits
- Patient-Controlled Analgesic Infusion Pumps
- Disposable Infusion Pumps
- Tracheostomy Tube Kits
- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Drainage Catheter Sets
- Transradial Introducer Sets
- Introducer Needles
- I.V Cannulas
- Cervical Ripening Balloon
- Postpartum Balloon

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139711 0001
Report No.: 17047213 009

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Manifolds
- Stopcocks
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Manifold Sets
- Infusion Sets with Needleless Adapters
- Connecting Tubings
- Pressure Bandages
- Hemostasis Valve Sets

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05