Digitally signed by Trocin Caterina
Date: 2021.07.08 10:42:55 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	: Sterilmed Medical Elektrik Elektronik Otomasyon İnşaat Gıda Sanayi ve Dış Ticaret Ltd. Şti.
Company Address	: Başkent Organize Sanayi Bölgesi 18.Cadde No:43 Malıköy Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Steam Sterilizer - Class IIb
GMDN	: 38671
	Product Types are attached.
Certificate Number	: M.2018.106.10200
Report Number	: MD.3655.IB
Initial Assessment Date	: 27.02.2018
Registration Date	: 08.08.2018
Revision Date /No	: 24.03.2021/01
Expiry Date	: 07.08.2023

UDEM APPROVED 2292

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

This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.10200 and with the registration date of 08.08.2018 and with the revision date of 24.03.2021 issued for Sterilmed Medical Elektrik Elektronik Otomasyon İnşaat Gıda Sanayi ve Dış Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş." that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Steam Sterilizer – Class IIb	GMDN
SMA-DSD-160, SMA-DSD-200, SMA-DSD-250, SMA-DSD-300, SMA-DSD-300A, SMA-DSD-450, SMA-DSD-540, SMA-DSD-675, SMA-DSD-810, SMA-DSD-945, SMA-SSD-160, SMA-SSD-200, SMA-SSD-250, SMA-SSD-300, SMA-SSD-300A, SMA-SSD-450, SMA-SSD-540, SMA-SSD-675, SMA-SSD-810, SMA-SSD-945, SMA-VD-160, SMA-VD-200, SMA-VD-250, SMA-VD-300, SMA-VD-300A, SMA-VD-450, SMA-VD-540, SMA-VD-675, SMA-VD-810, SMA-VD-945, SMA-VD-75, SMB-DSD-160, SMB-DSD-200, SMB-DSD-250, SMB-DSD-300, SMB-DSD-300A, SMB-DSD-450, SMB-DSD-540, SMB-DSD-675, SMB-DSD-810, SMB-DSD-945, SMB-SSD-160, SMB-SSD-200, SMB-SSD-250, SMB-SSD-300, SMB-SSD-300A, SMB-SSD-450, SMB-SSD-540, SMB-SSD-675, SMB-SSD-810, SMB-SSD-945, SMB-VD-160, SMB-VD-200, SMB-VD-250, SMB-VD-300, SMB-VD-300A, SMB-VD-450, SMB-VD-540, SMB-VD-675, SMB-VD-810, SMB-VD-945,SMB-VD-75	38671

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

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA

TS EN ISO 14001:2015 Çevre Yönetim Sistemi

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

Yukarıda belirtilen kuruluş BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. prosedürlerine göre standart şartlarını karşıladığını kanıtlamıştır.

Kapsam

Sterilizasyon cihazları ve kimyasalları (Otoklav, Etilen Oksit, Formaldehit), ameliyat masası, jinekoloji masası, paslanmaz çelikten imal edilen hastane ekipmanları, cerrahi alet yıkama makinası, plazma sterilizatör cihazı imalatı, satışı ve teknik servis hizmetleri sunumu ile merkezi sterilizasyon sistemi kurulumu.

Sertifika No: 1116-02

İlk Belge Tarihi 23.03.2020
Belge Geçerlilik Tarihi 22.03.2023

Belgelendirme Kuruluşu
BBS A.Ş.

Ankara, 23.03.2020

Belgelendirme BBS A.Ş. tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleştirilmiştir ve düzenli gözetim denetimlerine tabidir.

Çevre Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0021-YS

TÜRKAK BDS NO
YS-9950-0955

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr ve tbds.turkak.org.tr adreslerinden doğrulanabilir.
Belge üzerindeki karekod QR okuyucu ile okutularak da doğrulama yapılabilir.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA

TS EN ISO 9001:2015 Kalite Yönetim Sistemi

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

Yukarıda belirtilen kuruluş BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. prosedürlerine göre standart şartlarını karşıladığını kanıtlamıştır.

Kapsam

Sterilizasyon cihazları ve kimyasalları (Otoklav, Etilen Oksit, Formaldehit), ameliyat masası, jinekoloji masası, paslanmaz çelikten imal edilen hastane ekipmanları, cerrahi alet yıkama makinası, plazma sterilizatör cihazı imalatı, satışı ve teknik servis hizmetleri sunumu ile merkezi sterilizasyon sistemi kurulumu.

Sertifika No: 1116-01

İlk Belge Tarihi 23.03.2020
Belge Geçerlilik Tarihi 22.03.2023

Belgelendirme Kuruluşu
BBS A.Ş.

Ankara, 23.03.2020

Belgelendirme BBS A.Ş. tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleştirilmiştir ve düzenli gözetim denetimlerine tabidir.

Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0021-YS

TÜRKAK BDS NO
YS-F25C-C361

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr ve tbds.turkak.org.tr adreslerinden doğrulanabilir.
Belge üzerindeki karekod QR okuyucu ile okutulmak suretiyle de doğrulama yapılabilir.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA

TS EN ISO 13485:2016 Tıbbi Cihazlar Kalite Yönetim Sistemi

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

Yukarıda belirtilen kuruluş BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. prosedürlerine göre standart şartlarını karşıladığını kanıtlamıştır.

Kapsam

Sterilizasyon cihazları ve kimyasalları (Otoklav, Etilen Oksit, Formaldehit), ameliyat masası, jinekoloji masası, paslanmaz çelikten imal edilen hastane ekipmanları, cerrahi alet yıkama makinası, plazma sterilizatör cihazı imalatı, satışı ve teknik servis hizmetleri sunumu ile merkezi sterilizasyon sistemi kurulumu.

Sertifika No: 1116-03

İlk Belge Tarihi 23.03.2020
Belge Geçerlilik Tarihi 22.03.2023

Belgelendirme Kuruluşu
BBS A.Ş.

Ankara, 23.03.2020

Belgelendirme BBS A.Ş. tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleştirilmiştir ve düzenli gözetim denetimlerine tabidir.

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr adresinden doğrulanabilir.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

CERTIFICATE

Medical Devices Quality Management System as per TS EN ISO 13485:2016

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

Applies a management system in line with the above standard for the following scope

Sterilization equipment and chemicals (autoclave, ethylene oxide, formaldehyde), operating table, gynecological table, stainless steel manufactured hospital equipments, surgical tool washing machine, plasma sterilizer device production, sale and technical services presentation and central sterilization system installation.

Certificate No: 1116-03

Initial Certification	23.03.2020
Valid Until	22.03.2023

Certification Body
BBS A.Ş.

Ankara, 23.03.2020

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

The authenticity of this certificate may be verified at www.bbsas.com.tr.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

CERTIFICATE

Environmental Management System as per TS EN ISO 14001:2015

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

Applies a management system in line with the above standard for the following scope

Sterilization equipment and chemicals (autoclave, ethylene oxide, formaldehyde), operating table, gynecological table, stainless steel manufactured hospital equipments, surgical tool washing machine, plasma sterilizer device production, sale and technical services presentation and central sterilization system installation.

Certificate No: 1116-02

Initial Certification 23.03.2020
Valid Until 22.03.2023

Certification Body
at BBS A.Ş.

Ankara, 23.03.2020

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

Çevre Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0021-YS

TÜRKAK BDS NO
YS-9950-0955

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.
The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

CERTIFICATE

Quality Management System as per TS EN ISO 9001:2015

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.

Malıköy Başkent OSB Mah. 18. Cadde No: 43

06909 Sincan / ANKARA

Applies a management system in line with the above standard for the following scope

Sterilization equipment and chemicals (autoclave, ethylene oxide, formaldehyde), operating table, gynecological table, stainless steel manufactured hospital equipments, surgical tool washing machine, plasma sterilizer device production, sale and technical services presentation and central sterilization system installation.

Certificate No: 1116-01

Initial Certification	23.03.2020
Valid Until	22.03.2023

Certification Body
at BBS A.Ş.

Ankara, 23.03.2020

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0021-YS

TÜRKAK BDS NO
YS-F25C-C361

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.
The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA
www.bbsas.com.tr

Certificate of Conformity

Certification Number: HY20DC-205S

Shenzhen HuaYu Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Manufacture:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Factory:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Product:	Medical X ray imager
Model(s):	KND8900, KND9902, KND9900, KND6320
Rating(s):	220-240V~, 50Hz, Class I, 5A
Standard:	**EN 60601-1-2:2015** **EN 55011:2016+A1:2017+A11:2020** **EN 61000-3-2:2019** **EN61000-3-3:2013+A1:2019**

The above EUT has been merged by us and meets the requirements of the Council Medical Directive 93/42 / EC & Electromagnetic Compatibility Directive 2014/30/EU, and is only valid in relation to the report number: HY20DR-205S

CE

SHENZHEN HUAYU TESTING OF CERTIFICATION CO.,LTD. AUTHORIZED

Senior Manager

April 29, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460,
Dalang Street, Longhua New District, Shenzhen
Shenzhen HuaYu Test Technology Co.,Ltd. http://www.hyjctest.com

Certificate of Conformity

Certification Number: HY20DC-204S

Shenzhen HuaYu Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Manufacture:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Factory:	**Shenzhen Kenid Medical Devices Co.,Ltd.**
Address:	1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, China 518108
Product:	Medical X ray imager
Model(s):	KND8900, KND9902, KND9900, KND6320
Rating(s):	220-240V~, 50Hz, Class I, 5A
Standard:	**EN 60601-1:2006+Cor.:2010+A1:2013**

The above EUT has been merged by us and meets the requirements of the Council Medical Directive 93/42 / EC & Low Voltage Directive 2014/35 / EU, and is only valid in relation to the report number: HY20DR-204S

CE

SHENZHEN HUAYU TESTING OF CERTIFICATION CO.,LTD.

Senior Manager

April 29, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460,
Dalang Street, Longhua New District, Shenzhen
Shenzhen HuaYu Test Technology Co.,Ltd. http://www.hyjctest.com

INGEER CERTIFICATION ASSESSMENT SERVICES

管理体系认证证书

认证编号：117 19 Q0M 0132 R1S

兹证明 **深圳市柯尼达巨茂医疗设备有限公司**

统一社会信用代码 **91440300085922214U**

地址 **广东省深圳市宝安区石岩街道园美社区园岭路志泫翰工业园厂房 H 栋一楼东面**

经现场评审满足：ISO13485：2016 医疗器械质量管理体系要求

认证范围 **II 类 6830 医用 X 射线设备的生产**

核准：

初次发证：2016 年 11 月 17 日

复评发证：2019 年 11 月 14 日

有效期至：2022 年 11 月 16 日

上海英格尔认证有限公司

国家认监委批准号: CNCA-R-2003-117

电话: 400-182-9001/+86 21-51114700

网址: www.icas.org.cn

地址: 上海市徐汇区中山西路2368号

华鼎大厦801室 200235

关注英格尔微信平台

第一次监审	第二次监审	第三次监审

INGEER CERTIFICATION ASSESSMENT SERVICES

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 19 Q0M 0132 R1S

This is to certify the quality management systems of

Shenzhen Kenid Medical Devices Co., Ltd.

Unified Social Credit Code **91440300085922214U**

Location **1st Floor, Building H, Zhixuanhan Industrial Area, Shiyan Town, Baoan District, Shenzhen, Guangdong, China**

has been assessed and registered as meeting the requirements of

ISO13485: 2016<Medical device-Quality management systems - Requirements for regulatory purposes>

Scope of approval

Production of II Type 6830 Medical X-Ray Device

Signed by:

SHANGHAI INGEER CERTIFICATION ASSESSMENT CO.,LTD 证书专用章

First Certification: 17 Nov. 2016
Recertification Date: 14 Nov. 2019
Expiry Date: 16 Nov. 2022

Shanghai Ingeer Certification Assessment Co.,Ltd.

Certification and Accreditation Administration of PRC:CNCA-R-2003-117
Tel: 400-182-9001/+86 21-51114700
Web: www.icas.org.cn
Add: Room 801,HuaDing Mansion, 2368# West Zhongshan Rd., Xuhui District, Shanghai, China, 200235

Focus on icas WeChat platform

First Surveillance Audit	Second Surveillance Audit	Third Surveillance Audit

MED CERT®

Certification. Medical Only.

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

IMAGE Information Systems Europe GmbH
Lange Straße 16
18055 Rostock
Germany

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection, installation and servicing of

- **Digital image processing systems**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-02-22**
Expiry date: **2024-02-15**

Report No.: 3420FS18F
Procedure No.: QS – 3420
Certificate No.: 3420GB445210222A

Hamburg, 2021-02-22

MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-19630-04-00

MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC20QY20038R2M/46500

We hereby certify that

Jusha Display Technology Co., Ltd.

(This Main Certificate Contains 2 Sub-certificates)

Unified Social Credit Code: 9132010667492893XP

Nanjing Jusha Display Technology Co., Ltd:
Registered Address: Unit A, 8F, Building 01, No.301 Hanzhongmen Street, Gulou District, Nanjing, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Nanjing Jusha Commercial&Trading Co., Ltd.:
Registered Address：301 Room, No.301 Hanzhongmen Street, Gulou District, Nanjing, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Nanjing Jusha Medical Technology Co., Ltd.
Registered Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

YY/T 0287-2017 / ISO 13485:2016

The Quality Management System Applies in the following area:

Nanjing Jusha Display Technology Co., Ltd.: Design, Development and Manufacture of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales And Services of Imported Medical Instruments (Within the Scope of Qualification License)
Nanjing Jusha Commercial & Trading Co., Ltd.: Sales of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales and Services of Imported Medical Instruments (Within the Scope of Qualification License)
Nanjing Jusha Medical Technology Co., Ltd.: Sales of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales and Services of Imported Medical Instruments (Within the Scope of Qualification License)

Certified since: September 29, 2014 Valid from: July 24, 2020 Valid until: September 28, 2023

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.

Signed by: Lu Mei

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

D 0006766

2018年版

PD-730-165 EC Declaration of Conformity

The manufacturer IMAGE Information Systems Europe GmbH
Lange Str. 16
18055 Rostock, Germany
Tel.: +49 381 496 58 20
www.image-systems.biz | info@image-systems.biz

declares under its sole responsibility that the medical device stated as follows:

iQ-VIEW / PRO 3.1

is classified as **Class IIa** according to rules **10** and **16** of the Medical Device Directive 93/42/EEC, Annex IX.

The conformity assessment has been performed according to Annex II (4) of MDD 93/42/EEC based on the following elements:

- Conformity to the Essential Requirements according to Annex I of MDD 93/42/EEC
- Quality Management System for the products / product categories

Digital image processing systems

The license of certification is subject to surveillance by the Notified Body.

MEDCERT GmbH
Pilatuspool 2
20355 Hamburg, Germany
(Notified Body CE 0482)

Rostock, 2018-04-12

Dr. Arpad Bischof
Managing Director

EC Declaration of Conformity

Manufacturer:

VINNO Technology (Suzhou) Co., Ltd

5F Building A, 4F Building C, No.27 Xinfa Road, Suzhou Industrial Park, Suzhou, 215123 Jiangsu, China

whose single Authorized Representative:

Wellkang Ltd

The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

We, the manufacturer, herewith declare that the products

Product Name: **Ultrasound Diagnostic System**

Product Model Number or Designator:

VINNO G86, VINNO G86E, VINNO G86P, VINNO M86, VINNO M86E, VINNO M86P with probes as below:
G2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CE, D3-6CX, D4-9E, F4-9E, G4-9E, X4-9E, G3-9M, G4-9M, I4-IIT, I7-18L, U5-15L, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, X10-23L, S1-6P, G1-4P, G3-10PX, G4-12P

VINNO 75, VINNO 75E, VINNO 75P, VINNO G65, VINNO G65E, VINNO G65P, VINNO G80, VINNO M80, VINNO G60, VINNO X8, VINNO X9, VINNO 60, VINNO 70, VINNO 80 with probes as below:
G2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CX, D4-9E, G4-9E, X4-9E, G4-9M, I4-11T, U5-15L, X3-10L, X4-12L, X6-16L, X9-22L, S1-6P, G1-4P, G3-10PX

VINNO G55, VINNO G55E, VINNO G55P, VINNO M55, VINNO M55E, VINNO M55P, VINNO E35, VINNO E35E, VINNO E35P, VINNO G50, VINNO M50, VINNO E30, VINNO X5, VINNO X6, VINNO X7, VINNO X65, VINNO X55, VINNO X35 with probes as below:
G2-5C, F2-5C, X2-6C, B2-6C, S1-8C, S2-9C, D3-6C, D3-6CE, D3-6CX, D4-9E, F4-9E, G4-9E, X4-9E, G3-9M, G4-9M, I4-11T, U5-15LE, F4-12L, X4-12L, X3-10L, X6-16L, X9-22L, S1-6P, G1-4P, G3-10PX

VINNO 8, VINNO 6, VINNO 5, VINNO 6EXP, VINNO 6PRO, VINNO 5EXP, VINNO 5PRO, VINNO 3, VINNO 3EXP, VINNO 3PRO with probes and carts as below:
Probes: D3-6C, D3-6CE, D4-9E, F2-5CE, F4-9E, F4-12L, G1-4P, G2-5C, G4-9E, G4-9M, I4-11T, I7-18L, S1-6P, U5-15LE, X4-12L, X6-16L, X10-23L, X9-22L, G3-8M, G3-10P, G3-10PX, X6-16LG.
Carts: CART-F, CART-S

VINNO A6, VINNO A6e, VINNO A6p, VINNO A5, VINNO A5e, VINNO A5p, VINNO A3, VINNO A3p, VINNO A2, VINNO A2p, VINNO A1, VINNO A1p with probes and carts as below:
Probes: A2-5C, A3-6D, A4-9E, A4-9M, A4-12L, A1-4P
Carts: CART

VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P with probes as below:
D3-6C, D3-6CE, F4-9E, F4-12L, G1-4P, F2-5C, G4-9E, G4-9M and X4-12L

VINNO Q3E-3C, VINNO Q3-3C, VINNO Q3S-3C, VINNO Q5E-3C, VINNO Q5-3C, VINNO Q5S-3C, VINNO Q3E-7L, VINNO Q3-7L, VINNO Q3S-7L, VINNO Q5E-7L, VINNO Q5-7L, VINNO Q5S-7L, VINNO Q3E-2P, VINNO Q3-2P, VINNO Q3S-2P, VINNO Q5E-2P, VINNO Q5-2P, VINNO Q5S-2P

meet the provisions of Directives below and their transpositions in national laws which apply to it.

- Council directive 93/42/EEC concerning medical devices
- Council directive 2014/53/EU on radio equipment directive
- Directive 2011/65/EU of European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The medical device has been assigned to class IIa 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 V 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.: DD 60137559 0001
Issue date: 2019-05-22
Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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

Company: VINNO Technology (Suzhou) Co., Ltd.
Address: 5F Building A, 4F Building C, No.27 Xinfa Road, Suzhou Industrial Park, 215123, Jiangsu, China

Suzhou, 2020-07-20

Name: Xishui
Title: GM, VINNO Technology (Suzhou) Co., Ltd.

EC Certificate

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

Registration No.: DD 60137559 0001

Report No.: 15081806 011

Manufacturer:
VINNO Technology (Suzhou)
Co., Ltd.
5F Building A,4F Building C
No. 27 Xinfa Rd.
Suzhou Industrial Park
Suzhou
215123 Jiangsu
China

Products:
Ultrasound Diagnostic Systems

Replaces Approval, Registration No.: DD 60109994 0001

Expiry Date: 2024-05-27

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: 2020-07-20

Date: 2019-05-22

Notified Body

Fuxiu Sheng

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.