EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Sterilmed Medical Elektrik Elektronik Otomasyon İnşaat Gıda Sanayi ve Dış Ticaret Ltd. Şti.
Company Address	: Saraykent San. Sit.53.Cad. No:26 Kahramankazan ANKARA / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Steam Sterilizer - Class IIb
Models	: 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
GMDN	: 38671
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	: -
Expiry Date	: 07.08.2023

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 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 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. 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 currency 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

HPi Verification Services

EU-type Examination Certificate

This is to certify that the product listed below conforms to the requirements of the

Pressure Equipment Directive 2014/68/EU

Annex III Module B(prod)

Certificate Number	HPiVS/P1057-046-I-01
Date of Issue	20-Feb-2018
Date of Expiry	19-Feb-2028
Designer	**STERILMED MEDİCAL ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. VE DIŞ. TİC. LTD. ŞTİ** SARAY MAH. SARAYKENT SANAYİ SİTESİ 53. CAD. NO:26 Kahramankazan/Ankara/Turkey
Description of Pressure Equipment	Steam Sterilizer and Steam Generator Type: SMA-VD-75, SMA-DSD-160, SMA-DSD-200, SMA-DSD-250, SMA-DSD-300A, SMA-DSD-300, 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-300A, SMA-SSD-300, SMA-SSD-450, SMA-SSD-540, SMA-SSD-675, SMA-SSD-810, SMA-SSD-945, SMB-VD-75, SMB-DSD-160, SMB-DSD-200, SMB-DSD-250, SMB-DSD-300A, SMB-DSD-300, 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-300A, SMB-SSD-300, SMB-SSD-450, SMB-SSD-540, SMB-SSD-675, SMB-SSD-810, SMB-SSD-945 SMA-VD-75, SMA-DSD-160, SMA-DSD-200, SMA-DSD-250, SMA-DSD-300A, SMA-DSD-300, 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-300A, SMA-SSD-300, SMA-SSD-450, SMA-SSD-540, SMA-SSD-675, SMA-SSD-810, SMA-SSD-945, SMB-VD-75, SMB-DSD-160, SMB-DSD-200, SMB-DSD-250, SMB-DSD-300A, SMB-DSD-300, 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-300A, SMB-SSD-300, SMB-SSD-450, SMB-SSD-540, SMB-SSD-675, SMB-SSD-810, SMB-SSD-945
Drawing No	540.212.01-01 Steam Sterilizer, SM 75 VE 160 Steam generator, SM 200 250 300 VE 450 Steam generator, SM 540 VE 675 Steam generator, SM 810 VE 945 Steam generator
Design Pressure	PS = 2.7 bar (Steam sterilizer), PS = 3.5 bar (Steam generator)
Design Temperature	Max 144 °C
Standards Used	EN 13445-3:2014
Report Reference	HPiVS/P1057-046-DR01, HPiVS/P1057-046-1

This Certificate is valid in any European Economic Area Member State.

This Certificate has been issued by HPi Verification Services Ltd which is a body notified to the European Commission according to the provisions of the Pressure Equipment Directive (Notified Body number 1521).

This Certificate is issued following the assessment of a representative sample of the Pressure Equipment detailed above in accordance with the provisions of the above regulations. The equipment must be subject to an appropriate conformity assessment module during manufacture prior to the CE Mark being affixed.

Check this certificate is genuine

Managing Director

Technical Manager

CE

EU Notified Body No. 1521

Company registered in England #7217086

Tel +44 1491 822818
Fax +44 700 600 6831
Email enquiries@eucertification.com
www.eucertification.com

HPi Verification Services Ltd.
The Manor House
Howbery Park, Wallingford
OX10 8BA, United Kingdom

93/42/EEC-2007/47/EC Medical Devices Directive

DECLERATION OF COMFORMITY

Company Name : Sterilmed Medical Elektrik, Elektronik, Otomasyon, İnşaat, Gıda, Sanayi ve Dış Ticaret Ltd. Şti.

Address : Başkent Organize Sanayi Bölgesi 18.Cadde No:43 Maliköy Sincan Ankara -Türkiye

Tel / Fax : +90.312. 375 81 00/ +90.312. 375 92 92

Web / E-mail : www.sterilmed.com.tr / info@sterilmed.com.tr

We, as manufacturer of this product, herewith declare under our sole responsibility that the below mentioned products mentioned above:

Product : Steam Sterilizer

GMDN Code : 38671

Model Code :

Product	Brand	Model	GMDN Code	UNSPSC Code	Class
Steam Sterilizer	SMA SMB	DSD -160, DSD -200, DSD-250, DSD-300B, DSD-300, DSD-450, DSD-540, DSD-675, DSD-810, DSD-945, SSD-160, SSD-200, SSD-250, SSD-300B, SSD-300, SSD-450, SSD-540, SSD-675, SSD-810, SSD-945, VD-160, VD-200, VD-250, VD-300B, VD-300, VD-450, VD-540, VD-675, VD-810, VD-945, VD-75	38671	42281508	IIb

Classification : IIb (According to MDD, Annex IX – Excluding Section 4)

meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Directives : Medical Device Directive (MDD 93/42/EEC), Annex II (Excluding Section 4) and 200//47/EC Annex 2.3 requirements. MDD 93/42/EEC and 2007/47/EC Annex 2.3 (Excluding conformity assessment route Annex 4)

Standards : Standards applicable to this product are EN 60601-1, EN 60601-1-2, EN 62304, EN 60204-1, EN 285, EN 13445-1, EN15223-1, EN 62366, EN 14971, IEC 60529, EN 1041, EN 61010-2-40, EN 61010-1, EN ISO 13485, EN ISO 9001, EN ISO 14001

Notified Body : UDEM International Certification Auditing Training Centre Industry and Trade Co.

Mutlukent Mah. 2073. Sok. (Eski 93. Sok) No: 10 Çankaya / ANKARA / TURKEY

Burhan ZORLU
Company Manager
27.09.2019
Expiry Date: 07.08.2023 / Revision: 2019.05

UDEM 2292

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

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

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

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

DQS Holding GmbH has issued an IQNet recognized certificate that the organization

aycan Digitalsysteme GmbH

Innere Aumühlstraße 5
97076 Würzburg
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, distribution and service of software for medical use

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Issued on: 2018-11-12
Expires on: 2021-11-11

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration number: DE-381717 MP2016

Alex Stoichitoiu
President of IQNet

Michael Drechsel
Managing Director of DQS Holding GmbH

IQNet Partners*:

AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CERTIFICATE

This is to certify that the company

aycan Digitalsysteme GmbH

Innere Aumühlstraße 5
97076 Würzburg
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, distribution and service of software for medical use

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	381717 MP2016
Certificate unique ID	170718711
Effective date	2018-11-12
Expiry date	2021-11-11
Frankfurt am Main	2018-11-12

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

aycan Digitalsysteme GmbH

Innere Aumühlstraße 5
97076 Würzburg
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device family:	Product:	Class:
aycan workstation	aycan mobile	IIa
	aycan web	IIa

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	381717 MR2
Certificate unique ID	170766128
Effective date	2020-03-09
Expiry date	2024-05-26
Frankfurt am Main	2020-03-09

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

EC Declaration of Conformity

Manufacturer:

Nanjing Jusha Display Technology Co., Ltd.
8A, Block1. Nanjing International Service Outsourcing Mansion, No. 301 Hanzhongmen Street, Nanjing City, Jiangsu Province, 210036 China.
Tel: +0086-25-83305050
Fax: +0086-25-83302899

whose single Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
Tel：+31644168999
E-mail：peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Medical Display

Model：M550G, M550, JUSHA-M550G, JUSHA-M550

UMDNS-Code: **17960**

meet the provisions of 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 of European Union**. It bears the mark

CE

The product concerned has been manufactured following the procedure relating to the EC Declaration of Conformity set out in Annex VII 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: Nanjing Jusha Display Technology Co., Ltd.
Address: 8A, Block1. Nanjing International Service Outsourcing Mansion, No. 301 Hanzhongmen Street, Nanjing City, Jiangsu Province, 210036 China.

Nanjing 2020-10-28

Place, date

Legally binding signature, Function

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

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