E C C E R T I F I C A T E

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9909-2017-CE-ROC-NA-PS Rev. 1.0	PRJC-268377-2010-PRC-TWN	13 November 2022

This is to certify that the quality system of:

VADI Medical Technology Co., Ltd. Yangmei
No. 198, Lane 298, Huandong Rd., Zhongshan Village, Yangmei Dist., Taoyuan City 32665, Taiwan

For design, production and final product inspection/testing of:

Emergency Medical Care Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 01 February 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Palani Damodharan

This Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

VADI Medical Technology Co., Ltd.
Yangmei
No. 198, Ln. 298, Huandong Rd.
Zhongshan Village
Yangmei Dist.
Taoyuan City
32665
Taiwan

Holds Certificate Number: **MD 692156**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of respiratory gas humidifier, breathing system heater, resuscitator sets, connectors for breathing circuit, non-sterile medical tubing and filter, sterile single use breathing circuit, bacterial filter and electric power percussor.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-05-03
Latest Revision Date: 2019-10-04

Effective Date: 2019-10-16
Expiry Date: 2022-10-15

...making excellence a habit.™

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

EC Certificate Full Quality Assurance System: Certificate US19/819943403

The management system of

Sechrist Industries Inc.

4225 East La Palma, Anaheim, CA, 92807, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Gas Mixers for respiratory care and heart bypass oxygenation equipment, Monoplace Hyperbaric Chamber.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 14 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 18 May 1998
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered [illegible]

Authorised by

[illegible]
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545 48 48 f +32 (0)3 545 48 49 www.sgs.com

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