



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
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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 MEDICAL 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



EU Notified Body No. 1521
Company registered in England #7217086

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www.eucertification.com

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Howbery Park, Wallingford
OX10 8BA, United Kingdom



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 MEDICAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ.
GIDA SAN. VE DİŞ 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.



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

**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



**STERILMED MEDICAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ.
GIDA SAN. VE DİŞ TİC. LTD. ŞTİ.**

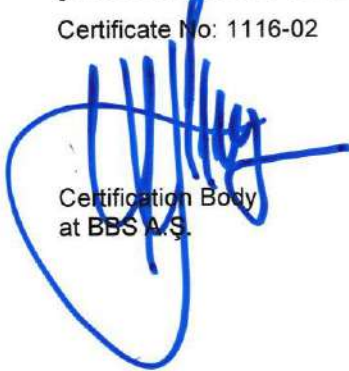
**Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA**

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.



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



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



**STERILMED MEDICAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞ.
GIDA SAN. VE DİŞ 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.

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