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

MDD EXTENSION APPROVAL LETTER

04/08/2023

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Regulation, we have issued an EC certificate on the date 08/08/2018 within the scope of the 93/42/EEC Medical Device Directive for the company and products whose information is given in Table-1. We declare that the certificate is valid for the products given in Table-1 before the expiry date of the relevant certificate.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
STERİLMED MEDİCAL ELEKTRİK EL. OTO. İNŞ. GID. SAN. VE DIŞ TİC. LTD. ŞTİ.	M.2018.106.10200	STEAM STERILIZER	07.08.2023

In order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated 02 April 2023 and numbered 32151, UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company. When the information provided by the company is reviewed, it has been shared that an application has been made to another notified body authorized under (EU) 2017/745 for the products given in Table-2 within the scope of the said EC certificate and/or the devices intended to replace it and/or a contract has been signed with the relevant notified body.

Table-2

Device	MDR NB	Date of Application	Date of Contract
STEAM STERILIZER	2696	26.04.2023	12.05.2023

In accordance with the Regulation Amending the Medical Device Regulation, for the products listed in Table-2, which are within the scope of the EC certificate for the above-mentioned company and are also under the MDR contract, unless undertaken by the other notified body after the MDR contract, we declare that we have undertaken the surveillance audit responsibility until 26 September 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 13/06/2023 as specified in Article 120 (3e) of the relevant Regulation. As of 26.05.2024, we do not have any surveillance responsibility for products that are within the scope of EC certificate but do not have an MDR application/contract.

The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

Serian DOMA
Medical Device Technical Regulation Responsible

UDEM ULUSLARARASI BELGELENDİRME
UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş.
Mutlukent Mah. 2073. Sk. No:10 Ümitköy - Çankaya / ANKARA
Tel: (0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 76
DOĞANBEY Vergi Dairesi : 885 044 25[illegible]

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	: Washer Disinfector - Class IIb
GMDN	: 35424

Product Types are attached.

Certificate Number	: M.2021.106.14377
Report Number	: MD.3655.IB
Initial Assessment Date	: 10.08.2020
Registration Date	: 19.03.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

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

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA
CERTIFICATE

TS EN ISO 9001:2015 Kalite Yönetim Sistemi
Quality Management System as per TS EN ISO 9001:2015

In accordance with BBS procedures, it is hereby certified that

STERİLMED MEDİCAL ELEK.OTOM.İNŞ.GIDA.SAN.DIŞ.TİC.LTD.ŞTİ.
Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.
Applies a management system in line with the above standard for the following scope

Kapsam	Scope
Sterilizasyon Cihazları ve Kimyasalları (Buharlı Sterilizatör), Ameliyat Masası, Jinekoloji Masası, Paslanmaz Çelikten İmal Edilen Hastane Ekipmanları, Cerrahi Alet Yıkama Makinası, Düşük Isı Sterilizatör Cihazları (Etilen Oksit, Formaldehit, Hidrojen Peroksit Plazma) İmalatı, Satışı, Pazarlanması ve Teknik Servis Hizmetleri Sunumu ile Merkezi Sterilizasyon Sistemi Kurulumu.	**Sterilization Devices and Chemicals (Steam Sterilizer), Operating Table, Gynecology Table, Hospital Equipment Made of Stainless Steel, Surgical Instrument Washing Machine, Low Temperature Sterilizer Devices (Ethylene Oxide, Formaldehyde, Hydrogen Peroxide Plasma) Manufacturing, Sales, Marketing and Technical Services Central Sterilization System Installation with Presentation.**

Sertifika No / *Ceritificate No* 1116-01

İlk Belge Tarihi / *Initial Certification* 23.03.2020
Belge Geçerlilik Tarihi / *Valid Until* 22.03.2026

Belgelendirme Kuruluşu / *Certification Body*
BBS A.Ş.

Ankara, 20.02.2024

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS 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-50EB-B593

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.
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 / TÜRKİYE
www.bbsas.com.tr

Rev.01-20.02.2024

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA
CERTIFICATE

TS EN ISO 13485:2016 Tıbbi Cihazlar Kalite Yönetim Sistemi
Medical Devices Quality Management System as per TS EN ISO 13485:2016

In accordance with BBS procedures, it is hereby certified that

STERİLMED MEDİCAL ELEK.OTOM.İNŞ.GIDA.SAN.DIŞ.TİC.LTD.ŞTİ.
Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.
Applies a management system in line with the above standard for the following scope

Kapsam

Sterilizasyon Cihazları ve Kimyasalları (Buharlı Sterilizatör), Ameliyat Masası, Jinekoloji Masası, Paslanmaz Çelikten İmal Edilen Hastane Ekipmanları, Cerrahi Alet Yıkama Makinası, Düşük Isı Sterilizatör Cihazları (Etilen Oksit, Formaldehit, Hidrojen Peroksit Plazma) İmalatı, Satışı, Pazarlanması ve Teknik Servis Hizmetleri Sunumu ile Merkezi Sterilizasyon Sistemi Kurulumu.

Scope

Sterilization Devices and Chemicals (Steam Sterilizer), Operating Table, Gynecology Table, Hospital Equipment Made of Stainless Steel, Surgical Instrument Washing Machine, Low Temperature Sterilizer Devices (Ethylene Oxide, Formaldehyde, Hydrogen Peroxide Plasma) Manufacturing, Sales, Marketing and Technical Services Central Sterilization System Installation with Presentation.

Sertifika No / *Ceritificate No* 1116-03

İlk Belge Tarihi / *Initial Certification* 13.03.2023
Belge Geçerlilik Tarihi / *Valid Until* 12.03.2026

Belgelendirme Kuruluşu / *Certification Body*
BBS A.Ş.

Ankara, 20.02.2024

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS auditing and certification procedures and is subject to regular surveillance audits.

Medikal Cihazlar
TS EN ISO 13485: 2016
AB-0021-YS

TÜRKAK BDS NO
YS-1A1A-A813

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.
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 / TÜRKİYE
www.bbsas.com.tr

Rev.02-20.02.2024

ZERTIFIKAT | CERTIFICATE | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA
CERTIFICATE

TS EN ISO 14001:2015 Çevre Yönetim Sistemi
Environmental Management System as per TS EN ISO 14001:2015

In accordance with BBS procedures, it is hereby certified that

STERİLMED MEDİCAL ELEK.OTOM.İNŞ.GIDA.SAN.DIŞ.TİC.LTD.ŞTİ.
Malıköy Başkent OSB Mah. 18. Cadde No: 43
06909 Sincan / ANKARA

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.
Applies a management system in line with the above standard for the following scope

Kapsam	Scope
Sterilizasyon Cihazları ve Kimyasalları (Buharlı Sterilizatör), Ameliyat Masası, Jinekoloji Masası, Paslanmaz Çelikten İmal Edilen Hastane Ekipmanları, Cerrahi Alet Yıkama Makinası, Düşük Isı Sterilizatör Cihazları (Etilen Oksit, Formaldehit, Hidrojen Peroksit Plazma) İmalatı, Satışı, Pazarlanması ve Teknik Servis Hizmetleri Sunumu ile Merkezi Sterilizasyon Sistemi Kurulumu.	**Sterilization Devices and Chemicals (Steam Sterilizer), Operating Table, Gynecology Table, Hospital Equipment Made of Stainless Steel, Surgical Instrument Washing Machine, Low Temperature Sterilizer Devices (Ethylene Oxide, Formaldehyde, Hydrogen Peroxide Plasma) Manufacturing, Sales, Marketing and Technical Services Central Sterilization System Installation with Presentation.**

Sertifika No / *Certificate No* 1116-02

İlk Belge Tarihi / *Initial Certification* 23.03.2020
Belge Geçerlilik Tarihi / *Valid Until* 22.03.2026

Belgelendirme Kuruluşu / *Certification Body*
BBS A.Ş.

Ankara, 20.02.2024

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS 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-93E7-760F

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.
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 / TÜRKİYE
www.bbsas.com.tr

Rev.01-20.02.2024

22/03/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER

CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0025/P1

Subject: Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

To whom it may concern,

This letteris the official document of UDEM A.Ş., a Notified Body (NB) designated in accordance with Regulation (EU) 2017/745 (MDR) and identified in NANDO with the number 2292, in accordance with the first subparagraph of Chapter 4.3 of Annex VII of the MDR and confirms that UDEM A.Ş. has received an application and has signed a written contract in accordance with the second subparagraph of Chapter 4.3 of Annex VII to the MDR with the following manufacturer:

Company Name:	STERİLMED MEDİCAL ELEKTRİK ELEKTRONİK OTOMASYON İNŞAAT SANAYİ VE DIŞ TİC.LTD. ŞTİ.
Company Address:	BAŞKENT ORGANİZE SANAYİ BÖLGESİ 18.CADDE NO:43 MALIKÖY SİNCAN ANKARA / TÜRKİYE
SRN Number (if any):	TR-MF-000018720

The devices covered by the above-mentioned official application and written contract are defined in the tables below. Table 1 describes the devices for which an MDR application has been received, a written contract has been made and UDEM A.Ş. is also responsible for the appropriate surveillance of the relevant devices within the scope of the 93/42/EEC Medical Device Directive (MDD). Table 2 identifies devices for which an MDR application has been received and a written contract has been concluded, but for which UDEM A.Ş. has not yet taken appropriate surveillance responsibility for the relevant devices under the MDD.

For devices covered by certificates issued under the MDD which expire after 26 May 2021 and before 20 March 2023 without withdrawal, this letter also confirms that the manufacturer has provided evidence that the competent authority of the Member State under the MDR up to the date of expiry of the MDD certificate has granted an exception or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of the MDR or Article 97(1) of the MDR for the devices concerned until 20 March 2023.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in a sterile condition or with a measurement function,
- 31 December 2028 for devices for which the conformity assessment procedure in accordance with Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure in accordance with the MDR requires the involvement of a notified body.

UDEM A.Ş. General Manager Name-Surname:	Mustafa Mumcuoğlu
Date:	22.03.2024
Stamp-Signature:	UDEM ULUSLARARASI BELGELENDİRM UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş Mutlukent Mah. 2073. Sk. No:10 Ümitköy Çankaya/ANKARA Tel: (0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 7 DOĞANBEY Vergi Dairesi: 885 044 258

Table-1 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
STEAM STERILIZER DEVICE	Class IIa devices	N/A	Certificate 1: M.2018.106.10200 Certificate 1: 2292
WASHING AND DISINFECTION DEVICE	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2021.106.14377 Certificate 1: 2292
LOW TEMPERATURE STERILIZER DEVICE	Class IIa devices	N/A	Certificate 1: M.2021.106.14635 Certificate 1: 2292

Tablo-2 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Not Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

CONTRACT CONFIRMATION LETTER REVISION HISTORY

Date	Contract Confirmation Letter Revision Number	Revision Explanation
22/03/2024	CL.CONTRACT.UDEM.0025/P1	Preparation of contract confirmation letter

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Ümitköy Çankaya/Ankara
0(312) 443 03 90
mdr@udem.com.tr