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

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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

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