Digitally signed by Jighili Tatiana
Date: 2023.10.18 16:57:11 EEST
Reason: MoldSign Signature
Location: Moldova

EC CERTIFICATE

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name	: Medtim Grup Medikal Malzemeleri Danışmanlık Bilgisayar Yazılım İnşaat İmalat San. ve Tic. Ltd. Şti.
Company Address	: Uzayçağı Cad. 1138. Sk. No:16 Ostim Yenimahalle ANKARA / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Disposible, Battery operated, Surgical/Orthopedic Lavage System With Accessories (With/Without Light) - Class IIa
GMDN	: 47890
Certificate Number	: M.2018.106.9150
Report Number	: MD.3244.IB
Initial Assessment Date	: 11.11.2017
Registration Date	: 04.01.2018
Revision Date /No	: -
Expiry Date	: 03.01.2023

APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex V, 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 V, section 4 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

UDEM

Addres: 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

01/06/2023

To whom It May Concern,

Operating as a notified body within the scope of the 93/42/EEC Medical Device Directive, we, UDEM A.Ş. hereby declare that we have issued an EC certificate on 04/01/2018 within the scope of 93/42/EEC Medical Device Directive for the company whose information is given in Table 1, and that the relevant certificate is valid until the expiry date of the certificate for the products given in Table 1.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
MEDTİM GRUP MEDİKAL MALZEMELERİ DANIŞMANLIK BİLGİSAYAR YAZILIM İNŞAAT İMALAT SAN. VE TİC. LTD. ŞTİ.	M.2018.106.9150	STERILE DISPOSIBLE, BATTERY OPERATED, SURGICAL / ORTHOPEDIC LAVAGE SYSTEM WITH ACCESSORIES (WITH/WITHOUT LIGHT)	03.01.2023

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 in order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates that expire before 20.03.2023. When the information provided by the company is reviewed, it is stated that a contract was made with another notified body authorized under (EU) 2017/745 on the date specified below, before the certificate expiry date for the products given in Table-2 within the scope of the EC certificate and / or the devices intended to replace it.

Table-2

Device	MDR NB	Date of Application	Date of Contract
STERILE DISPOSIBLE, BATTERY OPERATED, SURGICAL / ORTHOPEDIC LAVAGE SYSTEM WITH ACCESSORIES (WITH/WITHOUT LIGHT)	2696	29.12.2022	29.12.2022

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 04/05/2023 as specified in Article 120 (3e) of the relevant Regulation. We do not have any oversight responsibility for products that are within the scope of EC certificate but do not have an MDR 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 DEN. GÖZ. 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

T:+90 312 443 03 90 F: +90 312 443 03 76 E-mail: info@udem.com.tr
Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya / ANKARA