MDD EXTENSION APPROVAL LETTER

26/04/2023

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 13/04/2018 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
TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TİC. A.Ş.	M.2018.106.9536	-STERILE ANTIFOG SOLUTION -STERILE OBSTETRIC GEL -NONSTERILE LUBRICANT GEL -STERILE LUBRICANT GEL -NONSTERILE PARABEN-FREE LUBRICANT JEL	12.04.2023

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
-STERILE ANTIFOG SOLUTION -STERILE OBSTETRIC GEL -NONSTERILE LUBRICANT GEL -STERILE LUBRICANT GEL	2696	16.11.2022	17.11.2022

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

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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 25/04/2023 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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