AT SERTİFİKA

Üretim Kalite Güvence

93/42/AT Tıbbı Cihaz Direktifi Ek V

Firma Adı : Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.

Firma Adresi : Akçaburgaz Mahallesi, Muhsin Yazıcıoğlu Caddesi No:45/5, 34522 Esenyurt İSTANBUL / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek V

Ürünler : Non-Steril Gynosed Fertilite Jel - Sınıf IIa

GMDN : 34131

Sertifika Numarası : M.2021.106.14521
Rapor Numarası : MD.3561.IB
İlk Belgelendirme Denetimi : 08.12.2020
Tescil Tarihi : 04.05.2021
Revizyon Tarihi/No : -
Geçerlilik Tarihi : 27.05.2024

UDEM APPROVED 2292

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek V, gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek v madde 4'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. Ve Tic. A.Ş. 'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamanın kullanımı üretici beyanı ile firma sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udem.com.tr

EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Company Address	: Akçaburgaz Mahallesi, Muhsin Yazıcıoğlu Caddesi No:45/5, 34522 Esenyurt İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Non-Sterile Gynosed Fertilite Gel - Class IIa
GMDN	: 34131
Certificate Number	: M.2021.106.14521
Report Number	: MD.3561.IB
Initial Assessment Date	: 08.12.2020
Registration Date	: 04.05.2021
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 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 aforementioned directive. 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 dev,ce 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 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 validity of the certificate can be checked through www.udem.com. tr.

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

UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2024/05/20

TURKUAZ SAĞLIK HIZMETLERI MEDIKAL
TEMIZLIK KIMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.
Akçaburgaz Mah.
Muhsin Yazıcıoğlu Cad. No:45/5 34522
Esenyurt, İstanbul, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2024.MDR.1060-24-7.NBCL.0145

To whom it may concern,

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.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2024/03/20) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2024/03/20) with the following manufacturer:

TURKUAZ SAĞLIK HIZMETLERI MEDIKAL
TEMIZLIK KIMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.
Akçaburgaz Mah.
Muhsin Yazıcıoğlu Cad. No:45/5 34522
Esenyurt, İstanbul, Türkiye
SRN Number (if available): TR-MF-000015402

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has <u>not</u> yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
UDEM OIB:503730797..
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

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 other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

UDEM Adriatic d.o.o.
UDEM OIB:503730797
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

UDEM Adriatic d.o.o.
UDEM OIB:503730797
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (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

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (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
Fertility Gel	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2021.106.14521 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/20	2024.MDR.1060-24-7.NBCL.0145	Initial issue

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com