CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2019.106.12774-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti.
Company Address	: Malıköy Mah. Başkent Osb 19. Cad. No:54 Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Oxidized Regenerated Cellulose - Class III Sterile Polypropylene Mesh - Class IIb
GMDN	: 60300, 58298
	Product Types are attached.
Certificate Number	: M.2019.106.12774
Report Number	: MD.3902.IB
Initial Assessment Date	: 18.09.2019
Registration Date	: 16.10.2019
Revision Date /No	: -
Expiry Date	: 27.05.2024

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 applied 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 certificate 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 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 validity of the 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.

Digitally signed by Iarovoi Petru
Date: 2021.09.01 12:10:11 EEST
Reason: MoldSign Signature
Location: Moldova

Addres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
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E-mail: info@udemltd.com.tr www.udem.com.tr

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

2024/11/05

Altaylar Medikal Tıbbi Malzemeleri İnşaat Tekstil
Gida İthalat İhracat Sanayi ve Ticaret Ltd. Şti.
Maliköy Mah. Başkent OSB 19.Cad. No:54
Sincan, Ankara, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2024.MDR.1578.NBCL.0064/R01

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 2022/09/30) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/09/30) with the following manufacturer:

Altaylar Medikal Tıbbi Malzemeleri İnşaat Tekstil
Gida İthalat İhracat Sanayi Ve Ticaret Ltd. Şti.
Maliköy Mah. Başkent OSB 19.Cad. No:54
Sincan, Ankara, Türkiye
SRN Number (if available): TR-MF-000021519

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.

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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

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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
1.Polypropylene Mesh P900202/ 869898587TD012K	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.12774 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
2.Oxidized Regenerated Cellulose M040501/ 869898587TD02-S3G ORC Std, rule 8 **869898587TD02-F2N ORC Fibril** **869898587TD02-K2Y ORC Knit** **869898587TD02-P3A ORC Pillow**	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.12774 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design-Examination Certificate No: M.2019.106.12774-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

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
N/A	N/A	N/A	N/A

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/29	2024.MDR.1578.NBCL.0064	Initial issue
2024/11/05	2024.MDR.1578.NBCL.0064/R01	On the date of 2024/09/26, MDD surveillance of related legacy devices was transferred to UDEM Adriatic d.o.o from MDD Notified Body. For this reason related products have been moved from Table 2 to Table 1.

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Altaylar Medikal Tıbbi Malz. İnş. Teks. Gıda İth. İhr. San. ve Tic. Ltd. Şti.

Malıköy Mh.,Başkent OSB 19. cd, No: 54 Malıköy, Sincan,06909 Ankara, Türkiye

Tel: +90 312 387 3218 Faks: +90 312 387 3219 www.altaylarmedical.com

AT UYGUNLUK BEYANI
DECLARATION OF CONFORMITY

Tibbi Cihaz Direktifi / Medical Device Directive, 93/42/EEC

ALTAYLAR MEDİKAL TIBBİ MALZ. İNŞ. TEKS. GIDA İTH. İHR. SAN ve TİC. LTD.ŞTİ. Yetkili otorite UDEM (No:2292) tarafından değerlendirilmiştir. Bu deklarasyon, Tıbbi Cihaz Direktifi 93/42 EEC Ek VII ve Düzeltme 2007/47/EEC ile uyumlu olarak hazırlanmıştır.

ALTAYLAR MEDİKAL TIBBİ MALZ. İNŞ. TEKS. GIDA İTH. İHR. SAN ve TİC. LTD.ŞTİ. having been assessed by UDEM Notified Body N° 2292. This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC and Amendment 2007/47/EEC

Onaylanmış Kuruluş **Notified Body**	UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.		
Onaylanmış Kuruluş Adresi **Notified Body Address**	Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya - ANKARA		
Onaylanmış Kuruluş No **Notified Body Number**	2292		
Sertifikalar **Certificates**	**Sertifika No** **Certificate Number**	**Veriliş Tarihi** **Current Issue Date**	**Geçerlilik Tarihi** **Expiry Date**
EN ISO 13485:2016	85019	30.08.2019	31.08.2022
93/42 EEC Ek II / Annex II (Hariç 4/Except 4)	M.2019.10612774	16.10.2019	27.05.2024

ALTAYLAR MEDİKAL TIBBİ MALZ. İNŞ. TEKS. GIDA İTH. İHR. SAN ve TİC. LTD.ŞTİ. , Tıbbi Cihazlar Direktifinin maddelerine uygun olarak aşağıda belirtilen ürünler için bütün sorumluluğu üstlenir ve ürünün aşağıda belirtilen standartlara ya da diğer düzenleyici mevzuatlara uygunluğunu deklare eder.

ALTAYLAR MEDİKAL TIBBİ MALZ. İNŞ. TEKS. GIDA İTH. İHR. SAN ve TİC. LTD.ŞTİ. Declare under our sole responsibility that the products below to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of Medical Device Directive.

Ürün Sınıflandırması: 93/42/EEC Ek IX, Kural 8 Sınıf II-b
Product Classification: 93/42/EEC Annex IX, Rule 8 Class II-b

EN ISO 13485:2016 AC:2018	EN ISO 14644-1: 2015	EN ISO 10993-1:2020
EN ISO 15223-1: 2021	EN ISO 14644-2:2015	EN ISO 10993-3:2014
EN ISO 20417:2021	EN ISO 11737-1:2018	EN ISO 10993-4: 2017
EN ISO 14971:2019	EN ISO 11737-2:2020	EN ISO 11135:2014
EN ISO 11607-1:2020	EN ISO 11607-2: 2020	EN ISO 10993-5:2009
ISO 13934-1:2013	EN ISO 5084:1996	EN ISO 10993-6:2016
EN ISO 14155:2020	EN 868-5: 2018	EN ISO 10993-10:2013
ISO 14630:2012	ISO 527-1:2019	EN ISO 10993-11:2018
ASTM F1980 – 16:2016	MEDDEV 2.12/2 Rev.2:2012	MDD 93/42/EEC
ASTM F88/F88M:2015	MEDDEV 2.7/2:2015	TS EN 12127:1997
ASTM F1929:2015	MEDDEV 2.12/1 Rev.8:2013	TS ISO 2859-1:2012
MEDDEV 2.7/1 Rev.4: 2016	Version 1.22:2019	EU 722/2012
MEDDEV 2.4/1 Rev.9:2010	IEC 62366-1:2015 AMD:2020	NBOG BPG:2009-4
ISO TR 24971:2020		

No	Ürün Referansı Product Reference	Ürün Adı Product Name	GMDN	Sterilite Sterility	Risk Sınıfı Risk Class	Risk Kuralı Risk Rule
1	P1010, P1013, P2235, P1020, P1520, P0813, P1015, P1515, P1530, P0220, P2020, P2030, P2525, P2535, P3030, P0510, P0520, P0611, P0614, P7515, P0815, P0914, PP1515, PP4510, PP4510-H, PP0505-H, PP0505, PP0611, PP0611-H, PP0707, PP0707-H, PP75125, PP8515, P4545	POLİPROPİLEN MESH POLYPROPYLENE MESH	60300	Steril Sterile	Sınıf II-b Class II-b	Kural 8 Rule 8

Kalite Yönetim Temsilcisi ***Quality Management Representative***	**Genel Müdür** **General Manager**
Adı-Soyadı / Tarih -İmza **Name-Surname / Date-Sign** Birce Aydoğan 15.02.2022	**Adı-Soyadı / Tarih -İmza** **Name-Surname / Date-Sign** Paşa Altay 15.02.2022