



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2019.106.12774-1 Design 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 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.



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ABSORBABLE HEMOSTATS (Oxidized Regenerated Cellulose)		
Pahacel® Standard Absorbable Hemostat		
Reference	Size	Description
PCS11	1,25 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS12	1,3 cm x 5,1 cm	Pahacel® Standard Absorbable Hemostat
PCS13	1,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS14	2,5 cm x 2,5 cm	Pahacel® Standard Absorbable Hemostat
PCS15	2,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS16	5 cm x 7,5 cm	Pahacel® Standard Absorbable Hemostat
PCS17	5 cm x 35 cm	Pahacel® Standard Absorbable Hemostat
PCS18	5,1 cm x 7,6 cm	Pahacel® Standard Absorbable Hemostat
PCS19	5,1 cm x 35,6 cm	Pahacel® Standard Absorbable Hemostat
PCS20	7,5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
PCS21	10 cm x 20 cm	Pahacel® Standard Absorbable Hemostat
PCS22	10,2 cm x 20,3 cm	Pahacel® Standard Absorbable Hemostat
PCS23	15 cm x 23 cm	Pahacel® Standard Absorbable Hemostat
PCS24	12,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS25	5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
Pahacel® Knit Absorbable Hemostat		
Reference	Size	Description
PCK11	2,6 cm x 2,6 cm	Pahacel® Knit Absorbable Hemostat
PCK12	7,6 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK13	15,2 cm x 22,9 cm	Pahacel® Knit Absorbable Hemostat
PCK14	2,5 cm x 5,1 cm	Pahacel® Knit Absorbable Hemostat
PCK15	5,1 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK16	10,2 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK17	5 cm x 7,5 cm	Pahacel® Knit Absorbable Hemostat
Pahacel® Fibril Absorbable Hemostat		
Reference	Size	Description
PCF11	2,6 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF12	7,6 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF13	15,2 cm x 22,9 cm	Pahacel® Fibril Absorbable Hemostat
PCF14	2,5 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF15	5,1 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF16	10,2 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF17	5 cm x 7,5 cm	Pahacel® Fibril Absorbable Hemostat
Pahacel® Pillow Type Absorbable Hemostat (For Extra Hemostasis)		
Reference	Size	Description
PCE11	3 cm x 3 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE12	5 cm x 5 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE13	5 cm x 7,5 cm	Pahacel® Pillow Type Absorbable Hemostat
Polypropylene Mesh – Standard Type		
Order No	Size	
P1010	10x10 cm	



This document containing 2 (two) pages is the Annex of the Certificate with the number M.2019.106. 12774 and with the registration date of 16.10.2019 issued for "Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices

P1013	10x13 cm
P2235	22x35 cm
P1020	10x20 cm
P1520	15x20 cm
P0813	8x13 cm
P1015	10x15 cm
P1515	15x15 cm
P1530	15x30 cm
P0220	2x20 cm
P2020	20x20 cm
P2030	20x30 cm
P2525	25x25 cm
P2535	25x35 cm
P3030	30x30 cm
P0510	5x10 cm
P0520	5x20 cm
P0611	6x11 cm
P0614	6x14 cm
P7515	7,5x15 cm
P0815	8x15 cm
P0914	9x14 cm
P4545	45x45 cm
Polypropylene Mesh - Pre - Cut Shapes	
Order No	Size
PP0505	5x5 cm
PP0707	7x7 cm
PP0505-H	5x5 cm
PP0707-H	7x7 cm
PP4510	4,5x10 cm
PP0611	6x11 cm
PP4510-H	4,5x10 cm
PP0611-H	6x11 cm
PP75125	7,5x12,5 cm
PP8515	8,5x15 cm
PP1515	15x15 cm

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PCS15	2,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS16	5 cm x 7,5 cm	Pahacel® Standard Absorbable Hemostat
PCS17	5 cm x 35 cm	Pahacel® Standard Absorbable Hemostat
PCS18	5,1 cm x 7,6 cm	Pahacel® Standard Absorbable Hemostat
PCS19	5,1 cm x 35,6 cm	Pahacel® Standard Absorbable Hemostat
PCS20	7,5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
PCS21	10 cm x 20 cm	Pahacel® Standard Absorbable Hemostat
PCS22	10,2 cm x 20,3 cm	Pahacel® Standard Absorbable Hemostat
PCS23	15 cm x 23 cm	Pahacel® Standard Absorbable Hemostat
PCS24	12,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS25	5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
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PCE12	5 cm x 5 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE13	5 cm x 7,5 cm	Pahacel® Pillow Type Absorbable Hemostat



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

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AT UYGUNLUK BEYANI DECLARATION OF CONFORMITY

Tıbbi 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		
Sertifika 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	Adı-Soyadı / Tarih -İmza Name-Surname / Date-Sign
Birce Aydoğan 15.02.2022 	Paşa Altay 15.02.2022 



Certificate

ISO 13485 : 2016

**ALTAYLAR MEDİKAL TIBBİ
MALZEMELERİ İNŞAAT TEKSTİL
GIDA İTH. İHR. SAN. VE TİC. LTD. ŞTİ.**
Malıköy Mahallesi Başkent Osb. 19.Cadde No:54 Sincan/Ankara/TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

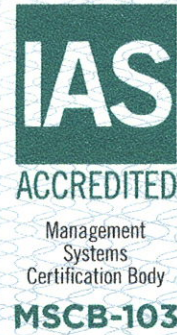
SCOPE

Desing, manufacture and sales of polypropylene mesh and absorbable hemostat(oxidized regenerated cellulose)

GROUP CODE

A -D

Certificate No : TC-75519
Registration Date : 22.08.2022
Reissue Date :
Expiry Date : 21.08.2023
Certificate Period : 3 Years (From the date of registration)
Exclusion : 7.5.3 / 7.5.4



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
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FR.86 Rev.4