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
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

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

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	

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
T:03124430390 F:03124430376 info@udemltd.com.tr www.udem.com.tr

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

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

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

akssert

CERTIFICATE

Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti.

Malıköy Mahallesi Başkent Osb 19. Cadde No:54 Sincan ANKARA / TURKEY

ISO 13485:2016

Scope: Design, manufacture and sales of polypropylene mesh and absorbable hemostat (oxidized regenerated Cellulose)

Hereby, AKSSERT Audit and Certification Ltd. Co., certificates that the above stated company gave the appropriate management system *according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is* effectively maintaned and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016

AKSSERT Audit and Certification Ltd. Co.

akssert JAS-ANZ

Certificate Number : 85019
Registration Date : 24.01.2019

Reissue Date : 30.08.2019
Expiry Date : 31.08.2022

Adres: Mustafa Kemal Mah. 2157/1 Sokak No:5/7 Çankaya / ANKARA– TÜRKİYE
Tel: +90 312 284 99 44 (pbx)
E-posta: info@akssert.com **Web:** www.akssert.com