# 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<br>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 |

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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 | |

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| | |
|---|---|
| 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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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2019.106.12774-1 and with the registration date of 16.10.2019 and with the revision date of 24.02.2021 issued for "Altaylar Medikal Tıbbi Malzemeleri 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 Directive.

| 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 |

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# EC DESIGN EXAMINATION CERTIFICATE

## 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2019.106.12774 the validity of the certificate M.2019.106.12774-1 will also end.

| | |
|---|---|
| Company Name | : Altaylar Medikal Tıbbi Malzemeleri 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 (Section 4) |
| Product | : Sterile Oxidized Regenerated Cellulose - Class III |
| GMDN | : 38771 |

Product Types are attached.

| | |
|---|---|
| Certificate Number | : M.2019.106.12774-1 |
| Report Number | : MD.3902.IB |
| Initial Assessment Date | : 18.09.2019 |
| Registration Date | : 16.10.2019 |
| Revision Date /No | : 24.02.2021/01 |
| Expiry Date | : 27.05.2024 |

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

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive 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 II, section 5 of the aforementioned directive. 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
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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2019.106.12774-1 and with the registration date of 16.10.2019 and with the revision date of 24.02.2021 issued for "Altaylar Medikal Tıbbi Malzemeleri 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 Directive.

| 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 |

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

**Altaylar Medical 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

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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**<br>**Notified Body** | UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. | | |
| **Onaylanmış Kuruluş Adresi**<br>**Notified Body Address** | Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya - ANKARA | | |
| **Onaylanmış Kuruluş No**<br>**Notified Body Number** | 2292 | | |
| **Sertifikalar**<br>**Certificates** | **Sertifika No**<br>**Certificate Number** | **Veriliş Tarihi**<br>**Current Issue Date** | **Geçerlilik Tarihi**<br>**Expiry Date** |
| EN ISO 13485:2016 | 85019 | 30.08.2019 | 31.08.2022 |
| 93/42 EEC Ek II / Annex II (except 4) | M.2019.106.12774 | 16.10.2019 | 27.05.2024 |
| 93/42 EEC Ek II / Annex II Section 4 | M.2019.106.12774-1 | 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 7 Sınıf III

**Product Classification:** 93/42/EEC Annex IX, Rule 7 Class III

| | | |
|---|---|---|
| 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 10993-5:2009 |
| EN ISO 11137-1:2015 A2:2019 | EN ISO 11607-1:2020 | EN ISO 10993-6:2016 |
| EN ISO 11137-2:2020 | EN ISO 11607-2:2020 | EN ISO 10993-10:2013 |
| EN ISO 14155:2020 | USP 39 NF 34 (2016) | EN ISO 10993-11:2018 |
| IEC 62366-1:2015 AMD:2020 | EN 868-5: 2018 | ASTM F1980 -16:2016 |
| MDD 93/42/EEC:2007 | MEDDEV 2.7/1 Rev.4:2016 | MEDDEV 2.12/1 Rev.8:2013 |
| MEDDEV 2.12/2 Rev.2:2012 | EN ISO 3071:2020 | EN ISO 14630:2012 |
| EN ISO 5084:1996 | MEDDEV 2.7/2:2015 | TS EN 2859-1:2012 |
| EU 722/2012 | Version 1.22:2019 | MEDDEV 2.4/1 Rev.9:2010 |
| NBOG BPG:2009-4 | ISO TR 24971:2020 | ASTM F88/F88M:2015 |
| ASTM F1929:2015 | | |

| No | Ürün Referansı<br>Product Reference | Ürün Adı<br>Product Name | GMDN | Sterilite<br>Sterility | Risk Sınıfı<br>Risk Class | Risk Kuralı<br>Risk Rule |
|---|---|---|---|---|---|---|
| 1 | PCS11, PCS12, PCS13, PCS14, PCS15, PCS16, PCS17, PCS18, PCS19, PCS20, PCS21, PCS22, PCS23, PCS24, PCS25 | Pahacel Okside Rejenere Selüloz Standart<br><br>Pahacel Oxidised Regenerated Cellulose Standard | 38771 | Steril<br><br>Sterile | Sınıf III<br><br>Class III | Kural 7<br><br>Rule 7 |
| 2 | PCK11, PCK12, PCK13, PCK14, PCK15, PCK16, PCK17 | Pahacel Okside Rejenere Selüloz Knit<br><br>Pahacel Oxidised Regenerated Cellulose Knit | 38771 | Steril<br><br>Sterile | Sınıf III<br><br>Class III | Kural 7<br><br>Rule 7 |
| 3 | PCF11, PCF12, PCF13, PCF14, PCF15, PCF16, PCF17 | Pahacel Okside Rejenere Selüloz Fibril<br><br>Pahacel Oxidised Regenerated Cellulose Fibril | 38771 | Steril<br><br>Sterile | Sınıf III<br><br>Class III | Kural 7<br><br>Rule 7 |
| 4 | PCE11, PCE12, PCE13, PCE14, PCE15, PCE16, PCE17, PCE18 | Pahacel Okside Rejenere Selüloz Pillow<br><br>Pahacel Oxidised Regenerated Cellulose Pillow | 38771 | Steril<br><br>Sterile | Sınıf III<br><br>Class III | Kural 7<br><br>Rule 7 |

| **Kalite Yönetim Temsilcisi**<br>***Quality Management Representative*** | **Genel Müdür**<br>**General Manager** |
|---|---|
| **Adı-Soyadı / Tarih -İmza**<br>**Name-Surname / Date-Sign**<br><br>Birce Aydoğan<br>01.02.2022 | **Adı-Soyadı / Tarih -İmza**<br>**Name-Surname / Date-Sign**<br><br>Paşa Altay<br>01.02.2022 |

PCA

PARTNERS CERTIFICATE ASSURANCE

# 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 |

IAS ACCREDITED

Management Systems Certification Body

MSCB-103

***PCA Certification Approval***

*PCA Sertifikasyon Hizmetleri Limited Şirketi*
*Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal / İSTANBUL*
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