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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., certifies 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 maintained and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com or 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.



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)

FRM.125/02-21.08.2019/20.02.2017

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CERTIFICATE

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 Tibbi 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 : -

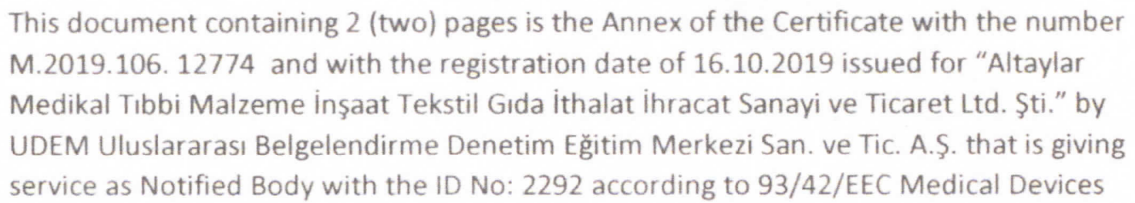
Expiry Date : 27.05.2024



UDEM 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 II 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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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

