

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHJECHISCHE REPUBLIK  
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE  
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021, grants the

## CERTIFICATE

No.: 8120009

for the Quality System in accordance with

### EN ISO 13485:2003

to the Firm

### ALTAYLAR MEDİKAL TIBBİ MALZEMELER İNŞ. TEKSTİL GIDA İTH. İHR. SAN. VE TİC. LTD. ŞTİ.

ATB İş merkezi No:222 Macunköy Yenimahalle, Ankara, Turkey

because it ascertained that the Quality System of the Firm in the field:


Designing, manufacturing and sales of polypropylene mesh, neurosurgical patties and eye pad

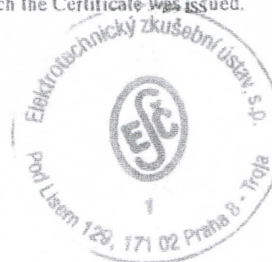
in the following locations: -

complies with all requirements of the above mentioned Standard documented by the Report No.: 105427-02 of: 03.01.2012

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.



  
Miroslav Sedláček  
Certification and Inspection Manager



Stamp



105427-02

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## CE - CERTIFICATE of full quality assurance system

No.: MED 120009

The Electrotechnical Testing Institute, Notified Body No. 1014, has decided that Quality System applied by

manufacturer

**ALTAYLAR MEDİKAL TIBBİ MALZEMELER İNŞ. TEKSTİL  
GIDA İTH. İHR. SAN. VE TİC. LTD. ŞTİ.  
ATB İş merkezi No:222 Macunköy Yenimahalle, Ankara, Turkey**

for design, manufacture and final inspection of medical devices

**Neurosurgical patties (PAHA, PASHA, WILLOCOTT) – class III  
Polypropylene mesh (PAHA, PASHA, WILLOMESH) – class IIb**

complies with provisions of Annex 2 section 3 of Governmental Order No. 336/2004 Coll. (Annex II section 3 of the Council Directive 93/42/EEC) incl. amendments.

This decision is based on the results presented in report No. 105427-03/01 of: 15.12.2011

In accordance with Art. 5 of Governmental Order No. 336/2004 Coll. (Art. 17 of Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.

The certified manufacturer is subject to a surveillance audit by the notified body in accordance with section 5 of Annex 2 of Governmental Order No. 336/2004 Coll. (Annex II section 5 of Directive 93/42/EEC) incl. amendments, and validity of the Certificate is subject to regular supervision. The manufacturer must inform the notified body about any intention resulting in significant modification of quality system or scope of included medical products. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

Edition 1



Prague

Miroslav Sedláček  
Certification and Inspection Manager



Stamp



105427-03