

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 190005

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer

BOZ TIBBİ MALZEME SANAYİ VE TİCARET ANONİM ŞİRKETİ
Sağlık Mahallesi Sağlık Sokak No:33/5 Sıhhiye Çankaya, Ankara, Turkey

for design, manufacturing and final inspection of medical device(s)

Non-absorbable surgical sutures and accessories - class III, See Annex

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **500537-01 of 29.07.2015, 803743-01 of 25.01.2019.**

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 21.02.2019 with validity until 09.11.2020

The validity of this Certificate is limited until: 09.11.2020

21.02.2019

Prague


Mgr. Miroslav Sedláček
Head of Certification Body



* C E R / M E D 1 9 0 0 0 5 *

500537-01

Certificate history

Date	Status	Reason
21.02.2019	Issuance	Replacement of certificate No. MED 150152



Non-absorbable surgical sutures and accessories – class III

Non-absorbable Surgical Sutures with double or single needle or without needle, Monofilament or Multifilament, EP metric 0,01 to 8, USP 12/0 to 6

Product	Material
Silk	Silk
Monamid/Multamid	Polyamide (PA)
Monoprolen *	Polypropylene (PP)
Monoflorid *	Polyvinylidene fluoride (PVDF)
Polivax/Polisil*	Polyester (PES)
Polytef*	Polyester (PTFE coated)
Monotef	PTFE
PTFE Pledgets;	PTFE, firm or soft, round, oval, square, rectangular
Tempowire	Temporary pace wire Stainless steel wire insulated with PE (polyethylene) or FEP (fluorinated ethylene polypropylene)

* May be supplied with pledgets (PTFE)

End of the list

