

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod Lisem 129, 171 02 Praha 8 - Troja

## EC DESIGN-EXAMINATION CERTIFICATE

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

No.: MED 100065

The Electrotechnical Testing Institute, Notified Body No. 1014, performed the design examination of medical device

**Sterile absorbable surgical sutures with or without atraumatic needle class III  
- Monolac, C-TEC Caprotec monofilament**

in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices  
(Annex II clause 4 of Directive 93/42/EEC) at

manufacturer **CHIRANA T. Injecta, s.r.o.**  
**Komořanská 2148, 143 00 Praha 4 - Modřany, Czech Republic**

and states that the design of medical device meets the provisions of Government Order No. 54/2015 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. 405686-02 of 24.03.2015, 503207-01 of 4.9.2015.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex I of Government Order No. 54/2015 Coll. (Annex I of Directive 93/42/EEC). In that case 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.

Edition 2

The first issue of this certificate from 18.9.2014 with validity until 31.5.2015  
The validity of this Certificate is limited until: 30.03.2020

31.3.2015 extension 15.09.2015

Prague

Mgr. Miroslav Sedláček  
Head of Certification Body



Stamp



405686-02