

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod líslem 129/2, 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 190025

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

Chiralen monofilament
Sterile synthetic non-absorbable surgical suture with or without atraumatic needle, class III

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. MED000018-10/01 of: 05.08.2019.

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 1 of Government Order No. 54/2015 Coll. (Annex 1 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 1

The first issue of this certificate from 13.08.2019 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague


Mgr. Miroslav Sedláček
Head of Certification Body



MED000018-10