



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

IQNet and CQS  
hereby certify that the organization

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

for the following field of activities

- **Design, production and delivery of sterile absorbable and non-absorbable surgical sutures with or without atraumatic needle and sterile non-absorbable and partially absorbable surgical meshes**

has implemented and maintains a

**Quality Management System**

which fulfills the requirements of the following standard

**ISO 13485 : 2003**

**Issued on: 2016 – 05 - 18**  
**Validity date: 2019 – 05 - 17**

**Registration Number: CZ – 66/2016**



Michael Drechsel  
President of IQNet

Tomáš Hruška  
President of CQS



**IQNet Partners\*:**

AENOR Spain AFNOR Certification France AIB-Vinçotte International Belgium APCER Portugal CCC Cyprus  
CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany  
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Quality Austria Austria RR Russia SIGE Mexico SII Israel SIQ Slovenia SIRIM QAS International Malaysia  
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IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod Lisem 129, 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 160017

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit has decided that the quality system limited to the production aspects related to securing and maintaining sterile conditions established at the

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

for medical device(s)

Sterile absorbable surgical sutures with atraumatic needles and without needles, Class III  
Sterile partially absorbable surgical meshes Capromesh, Class III  
List of models see enclosure

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 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. 401112-01 of 29.4.2014, 503207-01 of 25.8.2015, 504204-01/03 of 26.2.2016.

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.

Edition 1

The first issue of this Certificate from with validity until  
The validity of this Certificate is limited until: 29.04.2019

16.03.2016

Prague

Mgr. Miroslav Sedláček  
Head of Certification Body



Stamp



504204-01

**List of Medical Devices:**

**Class III:**

- Chirlac braided
- C-TEC Alfatec braided
- Chirlac rapid
- Chirasorb braided
- Chirasorb rapid braided
- Polydox
- C-TEC Cynadox monofilament
- Monolac
- C-TEC Caprotec monofilament
- Capromesh



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ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHHECHISCHE REPUBLIK  
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ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 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 160016

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit has decided that the quality system limited to the production aspects related to securing and maintaining sterile conditions established at the

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

for medical device(s)

**Sterile non-absorbable surgical sutures with atraumatic needles and without needles, Class IIb**  
**Sterile non-absorbable surgical meshes Chiralen, Class IIb**  
List of models see enclosure

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 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. 401112-01 of 29.4.2014, 503207-01 of 25.8.2015, 504204-01/02 of 26.2.2016.

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Edition 1

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Mgr. Miroslav Sedláček  
Head of Certification Body



Stamp



504204-01

**List of Medical Devices:**

**Class IIb:**

Chiralen

Chiraflon

Silon braided

Orsilon

Silon monofilament

C-TEC Celon monofilament

Silk braided, Silk twisted

Tervalon

Chiralen mesh



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