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**

Digitally signed by Ermicev Alexandr
Date: 2019.05.02 13:42:35 EEST
Reason: MoldSign Signature
Location: Moldova

Michael Drechsel
President of IQNet

Tomáš Hruška
President of CQS

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ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE 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.**
Komořanská 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

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

16.03.2016

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED160017

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

elektrotechnický zkušební ústav
ezú
Pod Lisem 129, 171 02 Praha 8 - Troja
-1-

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE 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 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.

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

elektrotechnický zkušební ústav ezú Pod Lisem 129, 171 02 Praha 8 - Troja -1-

16.03.2016

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 6 0 0 1 6 *

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

elektrotechnický zkušební ústav
ezú
-1-
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LABROMED LABORATOR