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 129/2, 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 190017

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

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

Sterile non-absorbable surgical sutures with atraumatic needles and without needles, class IIb
Sterile non-absorbable surgical meshes, 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 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. **MED000018-02/01 of: 05.08.2019**.

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 13.08.2019 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

Digitally signed by Ermicev Alexandr
Date: 2021.12.21 14:09:01 EET
Reason: MoldSign Signature
Location: Moldova

13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
Stamp

CER/MED190017

Class IIb:

Sterile non-absorbable surgical sutures with atraumatic needles and without needles

- Chiraflon monofilament
- Silon braided
- Orsilon braided
- Silon monofilament, C-TEC Celon monofilament
- Silk braided
- Silk twisted
- Tervalon braided
- Steel wire

Sterile non-absorbable surgical meshes

- Chiralen

End of the list

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja

Class IIb:

Sterile non-absorbable surgical sutures with atraumatic needles and without needles

- Chiraflon monofilament
- Silon braided
- Orsilon braided
- Silon monofilament, C-TEC Celon monofilament
- Silk braided
- Silk twisted
- Tervalon braided
- Steel wire

Sterile non-absorbable surgical meshes

- Chiralen

End of the list

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
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 190018

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

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

Sterile absorbable and non-absorbable surgical sutures with atraumatic needles and without needles, class III
Sterile partially absorbable surgical meshes, 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 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. **MED000018-03/01 of: 05.08.2019**.

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

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13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED190018

Class III:

Sterile absorbable surgical sutures with atraumatic needles and without needles

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

Sterile non-absorbable surgical sutures with atraumatic needles and without needles

- Chiralen monofilament

Sterile partially absorbable surgical meshes

- Capromesh

End of the list

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Třeja

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 129/2, 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 190018

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

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

Sterile absorbable and non-absorbable surgical sutures with atraumatic needles and without needles, class III
Sterile partially absorbable surgical meshes, 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 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. **MED000018-03/01 of: 05.08.2019**.

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 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

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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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 129/2, 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 190019

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

Chirlac braided, C-TEC Alfatec braided
Sterile synthetic 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. MED000018-04/01 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 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 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

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED190019

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
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Pod lisem 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 190020

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

Chirlac rapid braided
Sterile synthetic 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. MED000018-05/01 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 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 1

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The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

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CER/MED190020

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 129/2, 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 190021

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

Chirasorb braided
Sterile synthetic 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. MED000018-06/01 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 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 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

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

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

Pod lisem 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 190022

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

Chirasorb rapid braided
Sterile synthetic 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. MED000018-07/01 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 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 1

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The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED190022

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 129/2, 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 190023

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

Polydox monofilament, C-TEC Cynadox monofilament
Sterile synthetic 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. MED000018-08/01 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 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 1

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13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú Pod lisem 129/2, 171 02 Praha 8 - Troja -1-
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CER/MED190023

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
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Pod lisem 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 190024

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

Monolac monofilament, C-TEC Caprotec monofilament
Sterile synthetic 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. MED000018-09/01 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 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 1

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The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED190024

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 129/2, 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 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 1

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The validity of this Certificate is limited until: 26.05.2024

13.08.2019

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED190025

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 129/2, 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 190026

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

Capromesh
Sterile synthetic partially absorbable mesh, 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. MED000018-11/01 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 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 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

elektrotechnický zkušební ústav ezú -1- pod lisem 129/2, 171 02 Praha 8 - Troja
Stamp

* C E R / M E D 1 9 0 0 2 6 *

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 129/2, 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 190027

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

Chirasorb Plus braided
Sterile synthetic absorbable surgical suture with antibacterial coating 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. MED000018-12/01 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 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.

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elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
Stamp

* C E R / M E D 1 9 0 0 2 7 *

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CQS has issued an IQNet recognized certificate that the organization:

CHIRANA T. Injecta, s.r.o.

Komořanská 2148, Modřany, 143 00 Praha 4, Czech Republic

has implemented and maintains a

Quality Management System

for the following scope

- *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*

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 2019 – 05 – 18
Expires on: 2022 – 05 – 17

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: CZ – 64/2019

Alex Stoichitoiu
President of IQNet

Tomáš Hruška
President of CQS

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
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