Declaration of Conformity

/ Konformitätserklärung

Manufacturer / *Hersteller*: **SERAG-WIESSNER GmbH & Co. KG**

Address / *Adresse*: **Zum Kugelfang 8 - 12**

95119 Naila

Deutschland

Product - Model / *Produkt - Typ*:

Surgical suture made from polyglycolic acid and ε-caprolactone - SERAFAST® - dyed or undyed, in various gauge sizes and lengths, with various types of needles.

/ Chirurgisches Nahtmaterial aus Polyglykolsäure und ε-Caprolacton - SERAFAST® - gefärbt oder ungefärbt, in verschiedenen Fadenstärken u. -längen, mit unterschiedlichen Nadeltypen benadelt.

Articles / *Artikel* CE21:

4O07131L
4O07131S
4O073237
4P07321S
4O07131M
4O10131L
4O101312
4O101314
4O101376
4O103214
4O103276
4O10321L
4O15131L
4O15131M
4O15131N
4O151314
4O151333
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4O15322C
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4O153276
4O20131M
4O20131N
4O201314
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4O20321537
4O20322C
4O203236
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4O20324137
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4P203226

4O20321M
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JO073213
JO073212
JO07321L
JO10131L
JO103214
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JO15322C
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JP15322C
JO153215
JO203215
JO20322C
JO203241
JO203276
JO20412C
JO203214
JZ2048N2
JZ2048N1
JO303215
JO30322C
JO303241
4R07131M
4R07131S
4R10131L
4R103276
4R151314
4R15321M

4R203215
4R203236
4R303216
4R303242
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JR07321L
JR10131L
JR103276
JR15322C
JR203214
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JR203276
JR20412C
JR30322C
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Classification (MDD, Annex IX, Rule 8 with indent 3): **III**

/ Klasse (MDD, Anhang IX, Regel 8 mit Spiegelstrich 3)

We herewith declare under our sole responsibility that the above mentioned product meets the provisions of the following EC Council Directives and standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

/ Hiermit erklären wir unter unserer alleinigen Verantwortung, dass das o.g. Produkt die Forderungen der folgenden EG Richtlinien und Normen erfüllt. Alle entsprechenden Dokumentationsnachweise werden vom Hersteller und der Benannten Stelle bereitgehalten.

Directives and standards / *Richtlinien und Normen*

Annex II of Council Directive 93/42/EEC of 14.06.1993 concerning medical devices,

/ Anhang II der Richtlinie 93/42/EWG des Rates vom 14.06.1993 über Medizinprodukte,

Notified body / *Benannte Stelle*:

Elektrotechnický zkušební ústav, s. p.;

Pod Lisem 129,

171 02 Prague 8 - Troja, Czech Republic

ID-No.: 1014

Certificate No. / *Zertifikat Nr.*:

Design Examination / *Produktauslegung*: MED 200036

Quality Assurance / *Qualitätssicherung*: MED 200029

This declaration is valid until /

Diese Erklärung ist gültig bis: 26.05.2024

Place, Date / *Ort, Datum:* **Naila, 20.05.2021**

Signature / *Unterschrift:* .....

Name: **Stefan Pfeiffer**

Position: **President / *Geschäftsführer***

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 200029

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 — **Serag-Wiessner GmbH & Co. KG**
Zum Kugelfang 8-12, 95119 Naila, Germany

in manufacturing sites — **Serag-Wiessner GmbH & Co. KG**
Stegenwaldhauser Str. 6, 95152 Selbitz, Germany

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

Nonabsorbable sterile surgical sutures,
Absorbable sterile surgical sutures,
Absorbable sterile surgical mesh – class III, 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. **MED000073-01/01 of: 25.05.2020**.

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 28.05.2020 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

28.05.2020

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

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

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

MED000073-01

Certificate history

Date	Status	Reason
28.05.2020	Issuance	Replacement of certificate No. MED 150086

Absorbable and nonabsorbable sutures, absorbable mesh class III

Nonabsorbable sterile surgical sutures

- **SERAPREN**
- **SERALENE**
- **SERAMON/Keydent PTFE Suture, SERAMON CHORDAE LOOPS, PTFE Pledgets**
- **SERACOR, SULENE, TERYLENE**

Absorbable sterile surgical sutures

- **SERASYNTH, SERASYNTH LOC, SERASYNTH SlimSling**
- **SERAFAST**
- **SERAFIT, SERAPID**
- **SERAFIT PROTECT**

Absorbable sterile surgical mesh

- **SERASYNTH MESH**

End of 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 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 200036

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

Absorbable sterile surgical suture made from copolymer of glycolide and ε-caprolactone (PGACL) – class III, see Enclosure
SERAFAST

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 **Serag-Wiessner GmbH & Co. KG**
Zum Kugelfang 8-12, 95119 Naila, Germany

in manufacturing sites **Serag-Wiessner GmbH & Co. KG**
Stegenwaldhauser Str. 6, 95152 Selbitz, Germany

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. MED000073-09/02 of: 25.05.2020.

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 28.05.2020 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

14.05.2021

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú Pod lisem 129/2, 171 02 Praha 8 - Troja
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CER/MED200036

Certificate history

Date	Status	Reason
28.05.2020	Issuance	Replacement of certificate No. MED 150092
14.05.2021	Change	Change in the annex to the certificate

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Pod lisem 129/2, 171 02 Praha 8 - Troja

Absorbable suture class III

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End of list

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