Declaration of Conformance
/ *Konformitätserklärung*

Manufacturer / *Hersteller*:	**Serag-Wiessner GmbH & Co. KG**
Address / *Adresse*:	**Zum Kugelfang 8-12** **95119 Naila** **Deutschland**
European Representative: / *Europäischer Vertreter*	**not applicable** ***nicht anwendbar***

Product - Model / *Produkt - Typ*:

Surgical suture made from polytetrafluoroethylene - SERAMON® - undyed, in various gauge sizes and lengths, with various types of needles or non-needled. Specific articles according to list CE24
/ Chirurgisches Nahtmaterial aus Polytetrafluorethylen - SERAMON® - ungefärbt, in verschiedenen Fadenstärken u. -längen, mit unterschiedlichen Nadeltypen benadelt oder unbenadelt.
Artikelvarianten entsprechend Liste CE24

Classification (MDD, Annex IX): **III**
/ Klasse (MDD, Anhang IX)

We herewith declare under our sole responsibility that the above mentioned products meet 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 die o. g. Produkte die Forderungen der folgenden EG Richtlinien und Normen erfüllen. Alle entsprechenden Dokumentationsnachweise werden vom Hersteller und der Benannten Stelle bereitgehalten.

Directives and standards / *Richtlinien und Normen*

Council Directive 93/42 EEC of 14.06.1993 concerning medical devices
/ 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 150089** Quality Assurance / *Qualitätssicherung*: **MED 150086**
Date CE mark was affixed: / *Ausgabedatum der CE-Marke:*	**17.12.2012**
This declaration is valid until: / *Diese Erklärung ist gültig bis:*	**27.05.2020**
Place, Date / *Ort, Datum*:	**Naila, 10.06.2015**
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 TCHÉQUE
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 150086

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

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

Nonabsorbable surgical suture made from polyethylene terephthalate
Nonabsorbable surgical suture made from polypropylene
Nonabsorbable surgical suture made from polyvinylidene fluoride
Nonabsorbable surgical suture made from polytetrafluorethylene
Absorbable surgical suture made from polyglycolic acid
Absorbable surgical suture made from polydioxanone
Absorbable surgical suture made from PGACL (glycolic acid and ε-caprolactone),

class III	**Polyester Tape**	**Pledgets as accessories**
SERACOR®	**SERAPREN®**	**SERAFIT®**
SULENE®	**SERALENE®**	**SERAPID®**
TERYLENE	**SERAMON®**	**SERASYNTH®**
	Keydent® PTFE Dental Suture	**SERAFAST®**

Articles according to lists CE 04 – 05 – 12 – 24 – 02 –17 – 21

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 5 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. **501111 of: 28.05.2015**.

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 with validity until
The validity of this Certificate is limited until: 27.5.2020

28.5.2015

Prague

Miroslav Sedláček
Head of Certification Body

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

Stamp

* C E R / M E D 1 5 0 0 8 6 *

501111-01

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

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

Pod Lisem 129, 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 150089

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

Nonabsorbable surgical suture made from polytetrafluorethylene, class III
SERAMON®
Keydent® PTFE Dental Suture
Pledgets as accessories

Articles according to list CE24

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

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. 501111 of: 28.05.2015.

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 I 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 with validity until
The validity of this Certificate is limited until: 27.5.2020

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

28.5.2015

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 5 0 0 8 9 *

501111-04