Certificate

Standard ISO 14001:2015

Certificate Registr. No. 01 104 1400278

Certificate Holder:



SERAG-WIESSNER GmbH & Co. KG

Zum Kugelfang 8-12 95119 Naila Germany

Scope: Development, Construction of Surgical Sutures -

Textile Implants - Solutions

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 2020-08-05 until 2023-08-04.

First certification 2002

2020-07-21

LGA InterCert GmbH

Tillystr. 2 · 90431 Nuremberg





ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
3JEKTPOTEXHUYECKUЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

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

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021-1, grants the

CERTIFICATE

No.: 8210044

for the Quality Management System in accordance with

EN ISO 13485:2016

to the Firm

Serag-Wiessner GmbH & Co. KG

Zum Kugelfang 8-12, 95119 Naila, Germany

in localities:

Stegenwaldhauser Straße 6

95152 Selbitz

because it ascertained that the Quality Management System of the Firm in localities and processes:

Design, development, production and distribution of surgical sutures, reusable surgical instruments, non-active implantable devices, single use devices, textile implants, sterile solutions and gels.

complies with all requirements of the above mentioned Standard documented by the Report No.: 210634-01 of: 21.05.2021

The validity of the Certificate is limited till: 27.05.2024

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certificate granted: 28.05.2021

Prague

Ing. Radek Teufl Head of Certification Body





Abteilung: Z

F09355A Declaration of conformity QBD-N00624 zum Dokument 09355 Declaration of conformity #QBD-N00613

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 polyethylene terephthalate - SERACOR®, SULENE® and TERYLENE dyed or undyed, in various gauge sizes and lengths, with various types of needles or SULENE® and TERYLENE non-needled.

Chirurgisches Nahtmaterial aus Polyethylenterephthalat - SERACOR®, SULENE®, und TERYLENE - gefärbt oder ungefärbt, in verschiedenen Fadenstärken u. -längen, mit unterschiedlichen Nadeltypen benadelt oder SULENE® und TERYLENE unbenadelt.

Articles / Artikel CE04:

HN2B	HN56	HN35	HN5I	HN23
HN3K	HN4X	HN37	HN6A	HN4M
HN5S	HN6C	HN4K	HN6D	HN94
HN32	HN3H	HN4L	НN6Н	Q007171L
HN4I	НИЗЈ	HN46	HN6G	Q010171L
HN63	HN5K	HN66	HN6I	QO10171T
HN5H	HN2A	HN72	HN6J	Q0101711
HN6M	HN06	HN90	HN6L	QO101713
HN29	HN07	HN92	HN6N	QO103414
HN30	HN08	HN93	HN1D	QO103438
HN64	HN09	HN98	HN2P	QO15170D
HN2G	HN1A	HN99	HN24	QO15171L
HN5D	HN1G	HN4S	HN26	QO15171M
HN11	HN1Q	HN4V	HN44	QO15171T
HN2F	HN1U	HN4W	HN74	QO151713
HN2N	HN2L	HN4Q	HN5C	QO151714
HN21	HN2Z	HN5E	HN6P	QO151729
HN22	HN3M	HN5L	HN3C	QO151756
HN39	HN3S	HN5P	HN5F	QO151762
HN55	HN34	HN5U	HN20	QO151776

Gültig ab: 17.09.2019 Verteiler: FE; G; Q Freigabe: Pfeiffer, Stefan am 17.09.2019; Version: 3 **F09355A Declaration of conformity** zum Dokument 09355 Declaration of conformity #QBD-N00613

Q0152039	Q0303440	Q0503445	00151712	00203413
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QP153476	QN352100	QN603500	00151762	00203457
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QN200800	Q035341P	Q0703459	00153413	00203476
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 $\textbf{F09355A Declaration of conformity} \ zum \ Dokument \ 09355 \ Declaration \ of \ conformity \ \#QBD-N00613$

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OO303464 ON403800 NN152300 NN601900 OR103438 OO303476 ON405100 NO151713 NN603500 OR15171K OO304641 OO401715 NO151714 HR08 OR151729 ON351700 OO40717 NO153476 HR1G OR20171M ON351900 OO403415 NO153476 HR1Q OR201762 ON353500 OO403418 NN202300 HR26 OR203457 ON353800 OO403441 NO201711 HR2G OR301716 ON355100 OO403442 NO201713 HR30 OR301716 ON355110 OO403443 NO201713 HR30 OR350543 OO350543 OO403444 NO201713 HR30 OR350543 OO351714 OO403465 NO20342C HR4K OR403441 OO351715 OO403466 NO203457 HR6G OR603448 OO351716 OO404445 NO203476 HR6G OR603448 OO353416 ON501500 NN302100 HR6G OR603448 <tr< td=""><td>00303462</td><td>ON402200</td><td>NO101713</td><td>NO404466</td><td>OR07171S</td></tr<>	00303462	ON402200	NO101713	NO404466	OR07171S
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ON352100 O0403417 NN202100 HR20 OR202014 ON353500 O0403418 NN202300 HR26 OR203457 ON353800 OO403441 NO20171T HR26 OR301716 ON355100 OO403442 NO201713 HR30 OR30171K OO350543 OO403464 NO201715 HR35 OR353784 OO351714 OO403465 NO20342C HR4K OR403441 OO351715 OO403466 NO20342C HR4K OR503443 OO351716 OO403465 NO20342C HR6G OR603443 OO351716 OO403465 NO203476 HR6G OR603443 OO351717 OH402249 NO203476 HR6I QR204140 OO351717 OH402249 NO203476 HR6I QR300800 OO353414 ON503100 NN301900 HR6N QR603500 OO353417 ON505100 NN304000 NR301900 QR07171L OO353418 ON505100 NN304000 NR301900 QR70171L <t< td=""><td>ON351700</td><td>00401717</td><td>NO153414</td><td>HR1G</td><td>OR20171M</td></t<>	ON351700	00401717	NO153414	HR1G	OR20171M
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OO351717 OH402249 NO203476 HR6I QR204140 OO351736 ON501800 NN301900 HR6L QR300800 OO353414 ON502100 NN302100 HR6N QR403500 OO353415 ON503500 NN303800 MGR903500 QR603500 OO353416 ON505100 NN304000 NR301900 QR07171L OO353417 ON505700 NO301714 NR351900 QR103438 OO353418 OO502042 NO301715 NR503600 QR15170D OO353441 OO503418 NO303414 NR101713 QR201762 OO353443 OO503441 NO303415 NR151714 QR201762 OO353465 OO503465 NO303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR403417 OO353464 OO504618 NN353500 NR403481 QR403417 OO353466 OO504466 NO353415 NR101399 QR503758 OO353466 OO504466 NO353415 NR101399	OO351715	00403466	NO203441	HR5L	OR503443
OO351736 ON501800 NN301900 HR6L QR300800 OO353414 ON502100 NN302100 HR6N QR403500 OO353415 ON503500 NN303800 MGR903500 QR603500 OO353416 ON505100 NN304000 NR301900 QR07171L OO353417 ON505700 NO301714 NR351900 QR103438 OO353418 OO502042 NO301715 NR503600 QR15170D OO353441 OO503418 NO303414 NR101713 QR20171M OO353442 OO503441 NO303415 NR151714 QR201762 OO353443 OO503443 NO303441 NR201713 QR30171N OO353465 OO503466 NN351900 NR303414 QR353458 OO353464 OO504618 NN352100 NR353441 QR403417 OO353465 OP503435 NN353500 NR403481 QR403427 OO353466 OO504466 NO353415 NR101399 QR503758 OO353466 ON601900 NO353441 OR152238	00351716	00404445	NO203457	HR6G	OR603448
O0353414 ON502100 NN302100 HR6N QR403500 O0353415 ON503500 NN303800 MGR903500 QR603500 O0353416 ON505100 NN304000 NR301900 QR07171L O0353417 ON505700 NO301714 NR351900 QR103438 O0353418 O0502042 NO301715 NR503600 QR15170D O0353441 O0503418 NO303414 NR101713 QR20171M O0353442 O0503441 NO303415 NR151714 QR201762 O0353443 O0503443 NO303441 NR201713 QR30171N O0353465 O0503466 NN351900 NR303414 QR353458 O0353464 O0504618 NN352100 NR353441 QR403417 O0353465 OP503435 NN353500 NR403481 QR403427 O0353466 OP503442 N0353415 NR101399 QR503758 O0353728 ON601900 N0353443 OR301442 QR703459 O0355148 ON605100 NN403600 OR402249 <td>00351717</td> <td>OH402249</td> <td>NO203476</td> <td>HR6I</td> <td>QR204140</td>	00351717	OH402249	NO203476	HR6I	QR204140
O0353415 ON503500 NN303800 MGR903500 QR603500 O0353416 ON505100 NN304000 NR301900 QR07171L O0353417 ON505700 NO301714 NR351900 QR103438 O0353418 OO502042 NO301715 NR503600 QR15170D O0353441 OO503418 NO303414 NR101713 QR20171M O0353442 OO503441 NO303415 NR151714 QR201762 O0353443 OO503443 NO303441 NR201713 QR30171N O0353465 OO503465 NN351900 NR303414 QR353458 O0353464 OO504618 NN351900 NR353441 QR403417 O0353465 OP503435 NN353500 NR403481 QR403427 O0353465 OP503442 N0353415 NR101399 QR503758 O0353466 ON601900 N0353441 OR152238 QR603460 O0353728 ON601900 N0353457 OR402249 QR80342D O0355148 ON605100 NN403600 OR40400	00351736	ON501800	NN301900	HR6L	QR300800
OO353416 ON505100 NN304000 NR301900 QR07171L OO353417 ON505700 NO301714 NR351900 QR103438 OO353418 OO502042 NO301715 NR503600 QR15170D OO353441 OO503418 NO303414 NR101713 QR20171M OO353442 OO503441 NO303415 NR151714 QR201762 OO353443 OO503443 NO303441 NR201713 QR30171N OO353465 OO503465 NO303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR403417 OO353464 OO504618 NN352100 NR353441 QR403417 OO353465 OP503435 NN353500 NR403481 QR403427 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO355148 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403800 OR404000	00353414	ON502100	NN302100	HR6N	QR403500
O0353417 ON505700 NO301714 NR351900 QR103438 O0353418 OO502042 NO301715 NR503600 QR15170D O0353441 OO503418 NO303414 NR101713 QR20171M O0353442 OO503441 NO303415 NR151714 QR201762 OO353443 OO503443 NO303441 NR201713 QR30171N OO353456 OO503465 NN303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR403417 OO353464 OO504618 NN352100 NR353441 QR403417 OO353465 OP503435 NN353500 NR403481 QR403427 OO353466 OO504466 NO353415 NR101399 QR503758 OO353728 ON601900 NO353443 OR301442 QR703459 OO355748 ON605100 NN403600 OR402249 QR80342D OH402250 OO603448 NN403800 OR404000 QR30342C	00353415	ON503500	NN303800	MGR903500	QR603500
O0353418 O0502042 NO301715 NR503600 QR15170D O0353441 O0503418 NO303414 NR101713 QR20171M O0353442 O0503441 NO303415 NR151714 QR201762 O0353443 O0503443 NO303441 NR201713 QR30171N O0353456 O0503465 NO303457 NR20171T QR353441 O0353463 O0503466 NN351900 NR303414 QR403417 O0353464 O0504618 NN352100 NR353441 QR403417 O0353465 OP503435 NN353500 NR403481 QR403427 O0353466 OO504466 NO353415 NR101399 QR503758 O0353728 ON601900 NO353441 OR301442 QR703459 O0353784 ON603500 NO353457 OR402249 QR80342D O0355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	1	ON505100	NN304000	NR301900	QR07171L
O0353441 O0503418 NO303414 NR101713 QR20171M O0353442 O0503441 N0303415 NR151714 QR201762 O0353443 O0503443 NO303441 NR201713 QR30171N O0353456 O0503465 N0303457 NR20171T QR353441 O0353463 O0503466 NN351900 NR303414 QR353458 O0353464 O0504618 NN352100 NR353441 QR403417 O0353465 OP503435 NN353500 NR403481 QR403427 O0353466 O0504466 NO353415 NR101399 QR503758 O0353728 ON601900 NO353441 OR301442 QR703459 O0353784 ON603500 NO353457 OR402249 QR80342D O0355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353417	ON505700	NO301714	NR351900	QR103438
OO353442 OO503441 NO303415 NR151714 QR201762 OO353443 OO503443 NO303441 NR201713 QR30171N OO353456 OO503465 NO303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR353458 OO353464 OO504618 NN352100 NR353441 QR403417 OO35346437 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353418	00502042	NO301715	NR503600	QR15170D
OO353443 OO503443 NO303441 NR201713 QR30171N OO353456 OO503465 NO303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR353458 OO353464 OO504618 NN352100 NR353441 QR403417 OO3534637 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353441	00503418	NO303414	NR101713	QR20171M
OO353456 OO503465 NO303457 NR20171T QR353441 OO353463 OO503466 NN351900 NR303414 QR353458 OO353464 OO504618 NN352100 NR353441 QR403417 OO35346437 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353442	00503441	NO303415	NR151714	QR201762
OO353463 OO503466 NN351900 NR303414 QR353458 OO353464 OO504618 NN352100 NR353441 QR403417 OO35346437 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353443	00503443	NO303441	NR201713	QR30171N
OO353464 OO504618 NN352100 NR353441 QR403417 OO35346437 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	OO353456		NO303457	NR20171T	QR353441
OO35346437 OP503435 NN353500 NR403481 QR403427 OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353463	00503466	NN351900	NR303414	QR353458
OO353465 OP503442 NO353415 NR101399 QR503758 OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353464	00504618	NN352100	NR353441	QR403417
OO353466 OO504466 NO353441 OR152238 QR603460 OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	0035346437		NN353500	NR403481	QR403427
OO353728 ON601900 NO353443 OR301442 QR703459 OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353465	OP503442	NO353415	NR101399	QR503758
OO353784 ON603500 NO353457 OR402249 QR80342D OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353466	00504466	NO353441	OR152238	QR603460
OO355148 ON605100 NN403600 OR151900 QR153476 OH402250 OO603448 NN403800 OR404000 QR30342C	00353728	ON601900	NO353443	OR301442	QR703459
OH402250 O0603448 NN403800 OR404000 QR30342C				OR402249	QR80342D
		ON605100		OR151900	QR153476
ON401900 O0603467 NN405100 OR601900 QR503432				OR404000	QR30342C
	ON401900	00603467	NN405100	OR601900	QR503432

Classification (MDD, Annex IX, Rule 8 with indent 2): III

/ Klasse (MDD, Anhang IX, Regel 8 mit Spiegelstrich 2)

F09355A Declaration of conformity zum Dokument 09355 Declaration of conformity #QBD-N00613

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 200030

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:

Stefan Pfeiffer

Position:

Name:

President / Geschäftsführer

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Ullaile

Mgr. Miroslav Sedláček Head of Certification Body





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



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
3JEKTPOTEXHUYECKUЙ 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 200030

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

Nonabsorbable synthetic multifilament sterile surgical suture made of polyethylene terephthalate (PET), dyed or undyed, coated – class III, see Enclosure SERACOR, SULENE, TERYLENE

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. MED000073-02/02 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

12.05.2021

Prague

Milland

Mgr. Miroslav Sedláček Head of Certification Body





Certificate history

Date	Status	Reason
28.05.2020	Issuance	Replacement of certificate No. MED 150090
12.05.2021	Change	Change in the annex to the certificate



Nonabsorbable synthetic multifilament suture class III

SERACOR

HN2B					
HN5S	HN2B	HN56	HN35	HN5I	HN23
HN32	HN3K	HN4X	HN37	HN6A	HN4M
HN4I	HN5S	HN6C	HN4K	HN6D	HN94
HN63	HN32	HN3H	HN4L	HN6H	HR08
HN5H	HN4I	HN3J	HN46	HN6G	HR1G
HN6M	HN63	HN5K	HN66	HN6I	HR1Q
HN29	HN5H	HN2A	HN72	HN6J	HR20
HN30	HN6M	HN06	HN90	HN6L	HR26
HN64	HN29	HN07	HN92	HN6N	HR2G
HN2G	HN30	HN08	HN93	HN1D	HR30
HN5D HN1G HN4S HN26 HR4K HN11 HN1Q HN4V HN44 HR5L HN2F HN1U HN4W HN74 HR6G HN2N HN2L HN4Q HN5C HR6I HN21 HN2Z HN5E HN6P HR6L HN22 HN3M HN5L HN3C HR6N HN39 HN3S HN5P HN5F	HN64	HN09	HN98	HN2P	HR39
HN11	HN2G	HN1A	HN99	HN24	HR3S
HN2F HN1U HN4W HN74 HR6G HN2N HN2L HN4Q HN5C HR6I HN21 HN2Z HN5E HN6P HR6L HN22 HN3M HN5L HN3C HR6N HN39 HN3S HN5P HN5F	HN5D	HN1G	HN4S	HN26	HR4K
HN2N HN2L HN4Q HN5C HR6I HN21 HN2Z HN5E HN6P HR6L HN22 HN3M HN5L HN3C HR6N HN39 HN3S HN5P HN5F	HN11	HN1Q	HN4V	HN44	HR5L
HN21 HN2Z HN5E HN6P HR6L HN22 HN3M HN5L HN3C HR6N HN39 HN3S HN5P HN5F	HN2F	HN1U	HN4W	HN74	HR6G
HN22 HN3M HN5L HN3C HR6N HN39 HN3S HN5P HN5F	HN2N	HN2L	HN4Q	HN5C	HR6I
HN39 HN5P HN5F	HN21	HN2Z	HN5E	HN6P	HR6L
THE THE PERSON NAMED IN TH	HN22	HN3M	HN5L	HN3C	HR6N
HN55 HN34 HN5U HN20	HN39	HN3S	HN5P	HN5F	/ -
	HN55	HN34	HN5U	HN20	

SULENE

QO07171L	QN200800	QO301715	QO356926	QO504417
QO10171L	QN201900	QO30341N	QP353444	QP503432
QO10171T	QN202100	QO30341P	QN354300	QP503446
QO101711	QN202300	QO303415	QO3548R4	QN603500
QO101713	QN203500	QO303416	QN401900	QO603460
QO103414	QO20171M	QO30342C	QN402100	QO604460
QO103438	QO20171N	QO303440	QN403500	QO703459
QO15170D	QO201714	QO303441	QO403415	QO703460
QO15171L	QO201729	QO303443	QO403417	QN703400
QO15171M	QO201740	QO303462	QO403427	QO80342D
QO15171T	QO201756	QP303456	QO403441	QO80362D
QO151713	QO201762	QP30342C	QO403442	QO703760
QO151714	QO201774	QO303447	QO403443	MGN903500
QO151729	QO201776	QN351900	QO403447	MGN904500
QO151756	QO202276	QN352100	QO403448	MGN903600
QO151762	QO203404	QN353500	QO403465	MGN993500
QO151776	QO203414	QO351715	QO404426	Q3350346
QO152039	QO203415	QO35341P	QO407916	MGR903500
QO152214	QO203440	QO353415	QN501900	QR204140
QO153414	QO203476	QO353416	QN502100	QR300800
QO153415	QP203440	QO353417	QN503500	QR403500
QO153438	QP20171T	QO353441	QN504800	QR603500
QO153439	QN300800	QO353447	QO503441	QR07171L
QO153456	QN301900	QO353458	QO503445	QR103438
QO153476	QN302200	QO353463	QO503447	hnicky QR15170D
QP153476	QN303500	QO353465	QO503458	QR20171M
Q2150514	QO30171N	QO35483C	QO503460	QR201762
QH204140	QO301714	QO355146	QO503465	QR30171N

Milail 17.20 2 17.10

QR353441	QR403427	QR703459	QR30342C
QR353458	QR503758	QR80342D	QR503432
QR403417	QR603460	QR153476	

TERYLNE

OO07171S	OO20171K	OO303405	ON401900	NO201713
OO071712	OO20171M	OO30341M	ON402100	NO201714
OO071713	OO20171N	OO30341N	ON402200	NO201715
OO073438	OO20171T	OO303414	ON403500	NO20342C
ON102100	OO201713	OO303415	ON403800	NO203441
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OO101712	OO201715	OO303416	OO401715	NO203476
OO101713	OO20171537	OO303417	OO401717	NN301900
OO101714	OO201729	OO30342C	OO403415	NN302100
OO101756	OO201734	OO303436	OO403417	NN303800
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OO103461	OO201762	OO303457	OO403443	NO303414
OO103476	OO201763	OO303462	OO403464	NO303415
OH152238	OO201774	OO303463	OO403465	NO303441
ON151900	OO202014	OO303464	OO403466	NO303457
ON152100	OO203404	OO303476	OO404445	NN351900
ON152300	OO203413	OO304641	OH402249	NN352100
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OO15171L	OO203415	ON351900	ON502100	NO353415
OO15171M	OO203416	ON352100	ON503500	NO353441
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OO153415	ON303500	OO353418	ON605100	NR151714
OO153438	ON303800	OO353441	OO603448	NR201713
OO153440	ON305100	OO353442	OO603467	NR20171T
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OH201440	OO301713	OO353464	NN152300	NR101399
OH202276	OO301714	OO35346437	NO151713	OR152238
OH207038	OO301715	OO353465	NO151714	OR301442
ON201900	OO30171537	OO353466	NO153414	OR402249
ON202100	OO301716	OO353728	NO1534/6 cm	OK 151900
ON202200	OO301740	OO353784	NN202100	OR404000
ON202300	OO301762	OO355148	NN202300	OR601900
ON203500	OO302216	OH402250	NO20171T	OR702100

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OR073438	
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OR151729	
OR20171M	
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OR202014	

OR203457	
OR301716	
OR30171K	
OR350543	

OR353784
OR403441
OR503443
OR603448

End of list



F09355A Declaration of conformity QBD-N00624 zum Dokument 09355 Declaration of conformity #QBD-N00613

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 stainless steel - SERANOX® - in various gauge sizes and lengths, twisted or monofilament, coated or uncoated, with various types of needles or nonneedled.

/ Chirurgisches Nahtmaterial aus Stahldraht - SERANOX® - in verschiedenen Fadenstärken gezwirnt oder monofil, beschichtet oder unbeschichtet, unterschiedlichen Nadeltypen benadelt oder unbenadelt.

Articles / Artikel CE07:

	WO101714
	WO151714
	WO201715
,	WN201900
,	WN301900
	WN351900
7.1	WO351716
1	WO351765
١	WN351E00
١	WN401900
١	WN409A00
١	WO409959
١	WO401315
١	WN501900
١	WO501766
١	WO501316

	WU601768
	WO60146B
	WO601316
-	WO60136B
ŀ	WO70136B
	WO70146B
	WO70156B
	WO70351X
	WO70371X
	WO70341X
	WO80126B
	WO80136B
	WO80146B
	WO80156B
	WO80376B
	WP80146B

	WO90146B	
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7	WR351716	1
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	WO909C6B	
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Gültig ab: 17.09.2019 Verteiler: FE; G; Q Freigabe: Pfeiffer, Stefan am 17.09.2019; Version: 3

F09355A Declaration of conformity zum Dokument 09355 Declaration of conformity #QBD-N00613

Classification (MDD, Annex IX, Rule 8 without indent): IIb

/ Klasse (MDD, Anhang IX, Regel 8 ohne Spiegelstrich)

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: n.a.

Quality Assurance / Qualitätssicherung: MED 200038

This declaration is valid until /

Diese Erklärung ist gültig bis:

26.05,2024

F09355A Declaration of conformity zum Dokument 09355 Declaration of conformity #QBD-N00613

Place, Date / Ort, Datum: Naila, 20.05.2021

Signature / Unterschrift:

Stefan Pfeiffer

Position:

Name:

President / Geschäftsführer

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
3.JEKTPOTEXHUЧЕСКИЙ 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 200038

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 - class IIb, 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,

MED000073-12/03 of: 20.05.2020, MED000073-12/07 of: 27.05.2020, MED000073-12/11 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

13.05.2021

Prague

Milland

Mgr. Miroslav Sedláček Head of Certification Body





Certificate history

Date	Status	Reason
28.05.2020	Issuance	Replacement of certificate No. MED 150095
13.05.2021	Change	Change in the annex to the certificate



Nonabsorbable sterile surgical sutures class IIb made from

- polyamide (PA): SERALON (incl. cassette), SUPRAMID (incl. cassette), NYLON
- titanium coated polyamide: SERATAN
- stainless steel: SERANOX
- titanium coated stainless steel: SERANOX Ti
- silicone coated silk: **SERAFLEX** (incl. cassette)
- polyethylene therephthalate (PET): **POLYESTER TAPE**
- silicone coated polyethylene therephthalate: SULENE in cassette, TERYLENE in cassette

SERALON (incl. cassette) / SUPRAMID (incl. cassette) / NYLON

ZO010188	VO073413	VD158000	VO153476	VO20342N
ZO020188	VO073414	VN151900	VO153497	VO203434
ZO020275	VO073477	VN152300	VO154414	VO203440
ZO020289	VO073491	VO150614	VD208000	VO203441
ZO020294	VP073477	VO15171L	VN201900	VO203462
ZO020295	VP073491	VO15171M	VN202100	VO203463
ZO020594	VD108000	VO15171N	VO200614	VO203464
ZP02057E	VN101900	VO15171T	VO20171L	VO203476
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VO07341T	VO1017RE	VO153461	VO20341537	VO303414
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SERATAN

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FO10171T
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FO1517D3

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FR2017D5	

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SERANOX / SERANOX Ti

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WO909C6B	

SERAFLEX (incl. cassette)

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I	IC508400	
ŀ	IR308000	
ŀ	HR15171T	
ŀ	IR303441	
I	R308400	
I	R207038	

IR353417	
IR403417	
IR403464	
IR503443	
IR07341S	
IR15051L	

POLYESTER TAPE

MFN503400	
YN503400	
YU501753	
YU501754	

Y	V500554	
Y	V501153	
Y	V501154	
Y	V501155	

Y	V501753	
Y	V501754	
Y	V501755	
Y	V502854	

YV502860
YR503400
YR500554
YR502860

SULENE / TERYLENE in cassettes

QC108000	
QC158000	
QC208000	
QC308000	
QC358000	
QC408000	

Q	C50)84	00	
O	C10	080	00	
О	C15	580	00	
O	C20	080	00	
О	C30	080	00	
О	C35	580	00	

OC408000
OC508400
OC608400
OC708700
NC108000
NC158000

NC208	000
NC308	000
NC358	000
NC408	000
NC508	400
NC708	500

NR308000	
OR208000	
QR358000	

End of list





Surgical sutures for

CARDIO SURGERY

Surgical sutures









High-tech and handwork

For nearly 150 years, SERAG-WIESSNER has stood for surgical sutures of the highest quality. As the oldest established German manufacturer, the company combines decades of tradition with state-of-the-art technology. Extremely precise automated production technology is combined with the reliable and painstaking work of our experienced employees. In addition, we work closely together with medical professionals in both clinical practice and research.

This results in an extensive range of top-quality suture materials for cardiac surgery. These meet the precise demands for material and instruments that are used in cardiovascular procedures. Moreover, they have to give the surgeon sufficient scope in their application and should facilitate the surgical procedure.

SERACOR®

A suture material that offers high resilience and knot security has been developed for cardiac surgery. The result is SERACOR®, a braided polyester suture with an impressive structure and coating. The material is also physiologically inert. This ensures its long term stability with correspondingly good tissue tolerability.

Pledgets

Due to their oval and thinner shape, the latest generation of pledgets provide optimal adaptation to the body structures. This guarantees improved alignment. In addition, overlapping at the edges is avoided, thus averting the resultant risk of thrombus formation. Further advantages are less fraying and less narrowing of the lumen.



Needles

The needles in the SERAG-WIESSNER cardiac range are manufactured exclusively from 300 series steel. This material is outstanding for its special toughness combined with high ductility*. The sharply ground needle points also facilitate easier penetration with less force required.

Packaging

The respective needle sizes are easily recognisable through the transparent packaging. The needles and the sterile pack are both protected by the plastic foam fixings. Special punched-out recesses guarantee that the needle is easily grasped and the packaging dimensioning ensures safe handling.

Sternum wires - SERANOX®

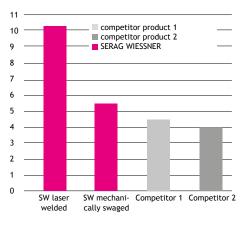
Modern laser techniques are applied in the production of the sternum wires. A firm and long-lasting connection is achieved through the new laser welding process. Sternum wires produced by this method have improved ductility* at the welded junction, are burr-free and permit the use of a strong needle pull-through force.

SERANOX® is a non-absorbable suture material that excels with its very high tensile strength and very low tissue reaction. The starting material is absolutely corrosion-resistant stainless steel.

Quality for the highest performance



Comparison of the ductility, EP8



^{*} A higher degree of tensile strength in the needle = greater safety during the operation.

Needle designation	Material	Size of pledgets/mm	Size USP	Size EP	Length of suture/metre	Units per box	Code number
LIDT 47	SERACOR green	_	4/0	1,5	1 x 0,75	24	HN3F
HRT-17	SERACOR green	-	3/0	2	1 x 0,73	24	HN3N
+HRT-17	SERACOR green	6 x 3 x 2	3/0	2	1 x 0,90	24	HN2S
	SERACOR green	-	2/0	3	1 x 0,75	24	HN11
	SERACOR green	6 x 3 x 2	2/0	3	1 x 0,75	24	HN55
	SERACOR undyed	6 x 3 x 2	2/0	3	1 x 0,75	24	HN54
	SERACOR green/undyed	-	2/0	3	4 x 0,75	12	HN72
	SERACOR green/undyed	6 x 3 x 2	2/0	3	4 x 0,75	12	HN09
	SERACOR green/undyed	3 x 2 x 1	2/0	3	8 x 0,75	6	HN1U
	SERACOR green/undyed	6 x 3 x 2	2/0	3	8 x 0,75	6	HN90
	SERACOR green/undyed	-	2/0	3	4 x 0,90	12	HN3I
	SERACOR green/undyed	6 x 3 x 2	2/0	3	4 x 0,90	12	HN3P
	SERACOR green/undyed	6 x 3 x 2	0	3,5	4 x 0,75	12	HN24
HRT-20	SERACOR green/undyed	-	2/0	3	4 x 0,75	12	HN78
HRT-20	SERACOR green	6 x 3 x 2	0	3,5	1 x 0,90	24	HN2D
+HRT-20	SERACOR undyed	6 x 3 x 2	2/0	3	1 x 0,75	24	HN94
	⊕ SERACOR green/undyed	6 x 3 x 2	3/0	2	4 x 0,90	12	HN2Y
\ \ \	SERACOR green/undyed	-	2/0	3	4 x 0,75	12	HN1G
	SERACOR green/undyed	6 x 3 x 2	2/0	3	4 x 0,75	12	HN08
	SERACOR green/undyed	6 x 3 x 2	2/0	3	8 x 0,75	6	HN93
	SERACOR green/undyed SERACOR green/undyed	- 4 y 2 y 2	2/0 2/0	3	$4 \times 0,90$ $4 \times 0,90$	12	HN2L HN34
	SERACOR green/undyed	6 x 3 x 2	0	3 3,5	4 x 0,90 4 x 0,75	12	HN2V
	SERACOR green/undyed	6 x 3 x 2	0	3,5	4 x 0,73 4 x 0,90	12 12	HN1D
LIDT 24	SERACOR green	6 x 3 x 2	2/0	3	1 x 0,75	24	HN56
(HRT-26) +HRT-26	SERACOR green	6 x 3 x 2	0	3,5	1 x 0,75	24	HN3H
	SERACOR green/undyed	-	2/0	3	4 x 0,75	12	HN06
	SERACOR green/undyed	6 x 3 x 2	2/0	3	4 x 0,75	12	HN07
	SERACOR green/undyed	6 x 3 x 2	2/0	3	8 x 0,75	6	HN37
	SERACOR green/undyed	6 x 3 x 2	2/0	3	4 x 0,90	12	HN35
	SERACOR green/undyed	-	2/0	3,5	4 x 0,90	12	HN62
	SERACOR green/undyed	6 x 3 x 2	0	3,5	4 x 0,90	12	HN26
	SERACOR green/undyed	-	0	3,5	8 x 0,90	6	HN44
	SERACOR green/undyed	6 x 3 x 2	0	3,5	8 x 0,90	6	HN60

Further combinations on request!

Needle designation	Material	Size USP	Size EP	Length of suture/metre	Units per box	Code number
STERNUM SUTURES						
HRT-40	SERANOX monofilament	4	1	2 x 0,45	12	WO409959
HRK-48	SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament SERANOX monofilament	5 5 5 5 6 6 6 6	7 7 7 7 7 8 8 8 8 8	1 x 0,45 3 x 0,45 4 x 0,45 6 x 0,45 1 x 0,75 1 x 0,45 3 x 0,45 4 x 0,45 6 x 0,45 4 x 0,75	12 12 12 12 12 12 12 12 12 12	W070136B W070126B W070146B W070156B W070346B W080136B W080126B W080146B W080156B W080376B
HS-40	SERANOX monofilament	2	5	1 x 0,50	12	WO501766
HS-57	SERANOX monofilament SERANOX monofilament	5 5	7 7	6 x 0,45 4 x 0,75	12 12	WO70151X WO70371X

Further combinations on request!