EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

Digitally signed by Dubalari Pavel
Date: 2021.06.25 08:44:13 EEST
Reason: MoldSign Signature
Location: Moldova

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 17 October 2019

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

For: DNV GL Presafe AS

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **13422-2018-CE-CZS-NA-PS Rev 2.0**

Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	Change of product name	2019-09-11
2.0	**Editorial change** **BICRIL changed to DACRIL** **BICRIL RAPID changed to DACRIL RAPID** **BICRIL 910 changed to DACRIL 910**	**2019-10-17**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
13422-2018-CE-CZS-NA-PS Rev 2.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that:

Sterile surgical sutures

Manufactured by:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 17 October 2019

For: DNV GL Presafe

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	Change of product name	2019-09-11
2.0	**Editorial change** **BICRIL changed to DACRIL** **BICRIL RAPID changed to DACRIL RAPID** **BICRIL 910 changed to DACRIL 910**	**2019-10-17**

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**
Sterile surgical sutures	III

Short description of the Medical Device:

Surgical sutures with or without needle.

DACRIL - Polyglycolic acid multifilament coated, absorbable
DACRIL RAPID - Polyglycolic acid multifilament coated, fast absorbable
DACRIL 910 - Poly(glycolide-co-Lactide) (90/10) multifilament coated, absorbable
PDO-x- Polydioxanone monofilament, absorbable
MONO-x- Poly(glycolide-co-caprolactone) (75/25) monofilament, absorbable
BIOPRO- Polypropylene monofilament, non-absorbable

All the sutures are sterilized by Ethylene Oxide.

EC Design Examination Certificate

Certificate No.:
13464-2018-CE-CZS-NA-PS Rev. 2.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000409145-PA-NA-CZE Rev. 2.0	PRJC-595657-2019-PRC-CZE	01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.

4 Vladiceasca Str. 077168 Snagov, Romania

For design, production and final product inspection/testing of:

STERILE SURGICAL SUTURES

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 02 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate Removing of HERNIPRO Polypropylene Meshes and Prosthesis. Previously in the certificate N.:11713-2017-CE-NA-PS rev.1.0	13 October 2020
1.0	Editorial change	13 October 2020
2.0	**Reintroduced old device names (covered by 11713-2017-CE-NA-PS Rev. 1.0 until 2020-03-11) NYLON MULTI and NYLON MONO**	**02 November 2020**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile surgical sutures	BIOSTER Polyester suture multifilament synthetic coated non-absorbable	IIb
	BIOSILK Silk suture multifilament natural coated non-absorbable	
	BIONIL MULTIx & **NYLON MULTI** Polyamide (tip 6.6) suture multifilament synthetic coated non-absorbable	
	BIONIL MONOx & **NYLON MONO** Polyamide (tip 6.6) suture monofilament synthetic non-absorbable	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

Certificate No.:	Project No.:	Valid Until:
10000409145-PA-NA-CZE Rev. 2.0	PRJC-595657-2019-PRC-CZE	01 November 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

Endoscopic instruments, HF-instruments and accessories,
Needle systems and Drainage systems
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500036
Report no.	P18-01361-131197
Stuttgart	2019-01-04

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1033500036 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
Drainage systems	Nasal Biliary Drainage Probes SU	IIa
Endoscopic instruments	Stone extraction Balloons SU	IIa
	Scissors RU	IIa
	Cytology Brushes SU	IIa
	Spray Catheters SU/RU	IIa
	Suture Punches RU	IIa
	Foreign Body Retrievers / Polyp Retrievers SU/RU	IIa
	Biopsy Forceps SU/RU	IIa
	Multi Band Ligation Device SU	IIa
Needle systems	Fibrin Application Needles SU/RU	IIa
	FNA Systems for ultrasound endoscopy SU	IIa
	Transbronchial Aspiration Needles SU	IIa
	Injection Needles SU/RU	IIa
Drainage systems	Biliary Stents SU	IIb
	Pancreatic Stents SU	IIb
	Self-expanding Stents SU (Biliary, Bronchial/Tracheal, Colonic, Duodenal, Esophageal)	IIb
HF-instruments and accessories	Handles incl. HF connector RU	IIb
	Cysto Gastro Sets SU	IIb
	Sphincterotomes SU/RU	IIb
	Polypectomy Snares, Mukosectomy Snares SU/RU	IIb
	HOT Biopsy Forceps SU/RU	IIb

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

endoscopic instruments
(see attachment)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500037
Report no.	P18-01361-131199
Stuttgart	2019-01-04

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1033500037 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
endoscopic instruments	E.R.C.P. Catheters SU/RU Suction / Flushing Catheters SU Stone Extraction Baskets SU/RU Lithotripsy Baskets / Lithotripsy Spirals SU/RU Guiding Catheters SU/RU Pushers SU/RU Stent Placement Sets SU/RU Biliary Dilation Catheters SU Polyp & Foreign Body Retriever "EasyCollect" SU Guide Wires SU/RU Dilation Balloons SU	I (steril)

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

design, development, production, storage and distribution of instruments and accessories for the diagnostic and therapeutic endoscopy

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2019-03-11
Valid until	2021-01-23
Registration no.	D1033500038
Report no.	P18-01361-131193
Stuttgart	2019-03-11

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
257642-2018-AQ-CZE-NA-PS rev. 2.0	PRJC-575485-2017-MSC-CZE	11 April 2019	11 April 2022

This is to certify that the management system of:

BIOSINTEX S.R.L.

4 Vladiceasca Str. 077168, Snagov, Ilfov County, Romania

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURING AND TRADE OF STERILE SURGICAL SUTURES, WITH/ WITHOUT NEEDLES.

Place and date:
Høvik, 01 February 2021

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
276614-2018-AQ-ROU-RvA

Initial certification date:
17 April 2008

Valid:
10 December 2020 - 15 November 2022

This is to certify that the management system of

BIOSINTEX S.R.L.

4 Vladiceasca Str.,RO 077168, Snagov, Ilfov County, Romania

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design, development, manufacturing and trade of sterile surgical sutures, with/ without needles.

Place and date:
Bucharest, 10 December 2020

MGMT. SYS.
RvA C 024

The RvA is a signatory to the IAF MLA

For the issuing office:
DNV GL – Business Assurance
169A Calea Floreasca, Building A, Office 2072, 4th Floor, RO 014472, 1st District, Bucharest, Romania

Daniel Savu
Management Representative

MED CERT®

Certification. Medical Only.

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection and distribution of medical devices for

- **Urology**
- **Gynecology**
- **Radiology**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2023-03-12**

Report No.: 1202FS27F
Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

Appendix of certificate

Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2024-05-27**

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB410200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB410200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®
Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB410200310

List of products / product categories included in the scope of certificate

Medical devices for Urology

- **Biopsy guns**
- **Catheters**
- **Catheter sets**
- **Guide wires**
- **Stone retrieval baskets**
- **Cannulas**
- **Dilators**
- **Ureteral stents**

– End of list –

MEDCERT®
Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2024-05-27**

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB415200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED/CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB415200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB415200310

List of products / product categories included in the scope of certificate

Medical devices for Urology

- **Catheters**
- **Catheter accessories**
- **Urine-drainage systems**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EC Certificate Full Quality Assurance System: US97/10879.01

The management system of

Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWMC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10879.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.
Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextStitch®,Capio™, Fixt®, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, EFx endo fascial closuresystem (abdominal access), Sterile, EFx shield fascial closure system (abdominal access), Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems,
Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers),Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery. Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certificate US97/10878.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 20. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016

Issue 20

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material. Manufacturing of sterile single use absorbable and non-absorbable sutures.

Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

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