

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**

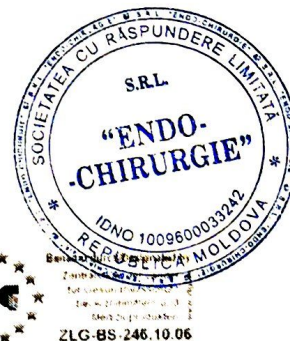
of 14 June 1993 concerning medical devices.

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



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>

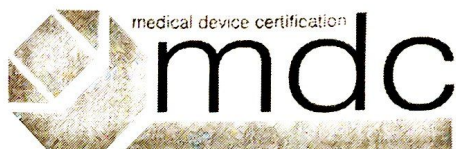
Attachment of the certificate

No. D1033500036

Date 2019-01-04

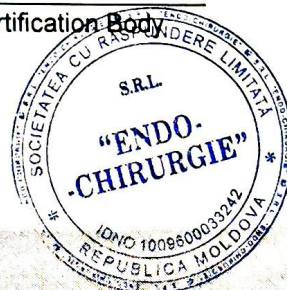
Page 1 of 1

Product category	Product	Class
Drainage systems	Nasal Biliary Drainage Probes SU	Ila
Endoscopic instruments	Stone extraction Balloons SU	Ila
	Scissors RU	Ila
	Cytology Brushes SU	Ila
	Spray Catheters SU/RU	Ila
	Suture Punches RU	Ila
	Foreign Body Retrievers / Polyp Retrievers SU/RU	Ila
	Biopsy Forceps SU/RU	Ila
	Multi Band Ligation Device SU	Ila
Needle systems	Fibrin Application Needles SU/RU	Ila
	FNA Systems for ultrasound endoscopy SU	Ila
	Transbronchial Aspiration Needles SU	Ila
	Injection Needles SU/RU	Ila
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



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[Signature]
 Head of Certification Body



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



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)



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>


Head of Certification Body



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



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 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

A stylized, handwritten signature in black ink, consisting of a large, looped 'R' followed by a horizontal stroke.

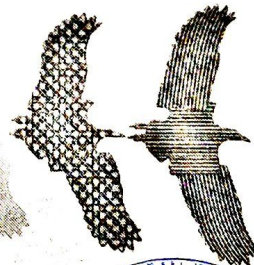


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SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



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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.

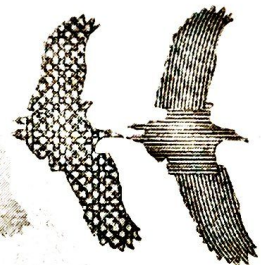
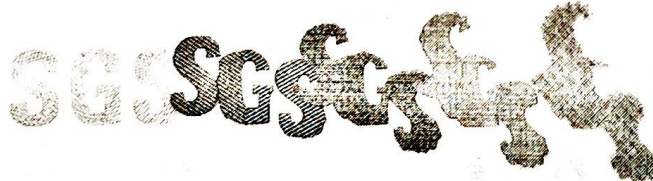
Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

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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Page 2 of 2



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.

CE 540596

Issued To:

**Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland**

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13**

Date: **2020-06-09**

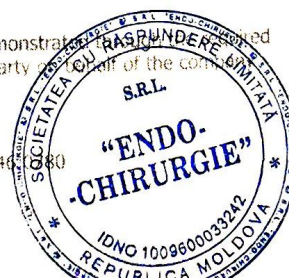
Expiry Date: **2024-05-26**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated by surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party named on this certificate, unless specifically agreed with BSI. This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 8000
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Sterile Intraosseous Vascular Access System	--
MD 1104	Non-sterile Intraosseous Vascular Access System	
MD 0102	Sterile Powered Bone Access	--
MD 1104	Non-sterile Powered Bone Access	
MD 0102	Sterile Sternal Intraosseous Device	--
MD 0101	Sterile Silicone Foley Catheter	--

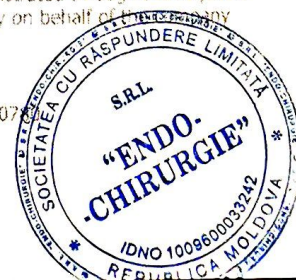
First Issued: **2009-01-13**Date: **2020-06-09**Expiry Date: **2024-05-26**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0700
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EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0301	Intraosseous Vascular Access System Stabilizer	--
MD 0102	Powered bone access connector	--
MD 0101	Tracheostomy Tube Accessories	--
MD 0102	Tuohy Borst Adaptor	--
MD 0102	Syringe	--
MD 0101	Urology Dilator	--
MD 0101	Guedel Airway	--
MD 0101	Intrauterine Catheter Set	--
MD 0101	Sterile Container	--
MD 0101	Neckband	--
Sterility aspects only		
---	Procedure Packs under article 12	---

First Issued: **2009-01-13**

Date: **2020-06-09**

Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

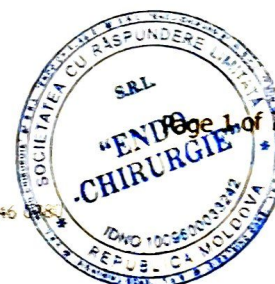
List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
ArcRoyal Virginia Road Kells, Co. Meath Ireland	Manufacture
Arriol International Corporation Carretera San Isidro KM 17 Zona Franca San Isidro Santo Domingo Este Dominican Republic	ETO Sterilization Manufacture
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	Manufacture
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	Radiation (Gamma Sterilization)

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
CeMed GmbH Im Oberdorf 41 72419 Neufra Germany	Assembly Packaging
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	Radiation (Gamma Sterilization)
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	Manufacture
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton MN 55112 USA	Manufacture

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist 42944 Taichung City Taiwan	Manufacture
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	Radiation (E Beam Sterilization)
Medical Service GmbH Luisenstraße 8 75378 Bad Liebenzell/Unterhaugstett Germany	Assembly Packaging

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:

Service(s) supplied

Medioplast Israel Ltd.
 7 Hayarkon St.
 P.O. Box 13214 Industrial Zone
 Yavne
 8122710
 Israel

ETO Sterilization

Rose GmbH für Medizintechnik
 Gottbillstraße 25-30
 54294 Trier
 Germany

ETO Sterilization

sfm medical devices GmbH
 Brückenstraße 5
 63607 Wächtersbach
 Germany

ETO Sterilization
Manufacture

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Sparton Onyx, LLC 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	Manufacture
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization

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Page 5 of 7

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Steritec, Inc. P.O. Box 1969 1705 Enterprise Street Athens, TX 75751 United States of America	ETO Sterilization
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	ETO Sterilization
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	ETO Sterilization

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 540596**
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IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	ETO Sterilization Manufacture
Viant San Antonio, Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 United States of America	Manufacture
Viant Upland, Inc. a.t.a. (formerly) Lake Region Medical 2052 West 11th Street Upland CA 91786 USA	Manufacture
Willy Rüsç GmbH Willy-Rüsç-Straße 4-10 71394 Kernen i.R., Germany	Manufacture

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: CE 540596
Date: 2020-06-09
Issued To: Teleflex Medical
 IDA Business and Technology Park
 Dublin Road
 Athlone
 Co. Westmeath
 Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325720	Company address amended. Extension to scope. Addition of Willy Rüscher, Germany as subcontractor for design and manufacture.
25 August 2009	7399908 7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope.
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal.

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Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as implemented through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Production Quality Assurance Certificate History

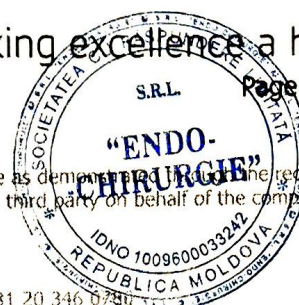
Certificate No: CE 540596
Date: 2020-06-09
Issued To: Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities.
23 May 2012	7778468	Correction of significant subcontractor address.
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC.
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC.

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Page 2 of 5

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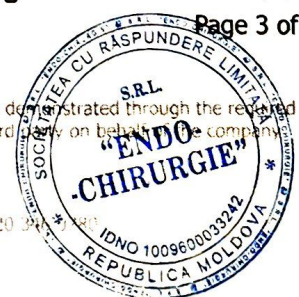
Date	Reference Number	Action
28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.
10 February 2016	8455693	Removal of Vidacare LLC from list of significant subcontractors. Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture. Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture. Removal of repeated use of word 'devices' from scope.
28 July 2017	8762518	Change of address for Coastal Life Technologies. Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors.
04 March 2019	7779566	Traceable to NB 0086.

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Page 3 of 5

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 31 99 1000
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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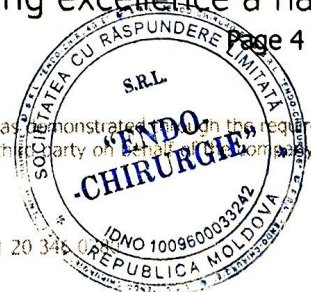
Date	Reference Number	Action
Current	3124053	<p>Certificate renewal.</p> <p>Addition of supplementary product information table.</p> <p>Update to scope to include non-active sterile urology catheters.</p> <p>Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc</p> <p>Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüsck GmbH.</p> <p>Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd.</p> <p>Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüsck GmbH.</p> <p>Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C.</p> <p>Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.</p>

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Page 4 of 5

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 344
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
	3124053	<p>Addition of Degania Silicone Limited for Manufacture</p> <p>Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Mediplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization</p> <p>Addition of Iotron Industries USA for E-beam Sterilization</p> <p>Addition of China Biotech Corporation and BBF Sterilisationservice GmbH for Gamma Sterilization.</p>

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive and demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party to the certificate company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

