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: 2022.05.03 13:09:11 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

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

By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 698961**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

In respect of:

The manufacture of Surgical Drapes.

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile surgical gowns, surgical drapes, surgical packs and examination gloves

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):

Albert Roossien, Regulatory Lead

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 698961

Issued To:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 0101	Transurethral Resection (T.U.R.) Drapes & Packs	N/A
Class Is		
MDS7006	Surgical Gowns	N/A
MDS7006	Surgical Drapes	N/A
MDS7006	Surgical Packs	N/A
MDS7006	Examination Gloves	N/A

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

By Royal Charter

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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Arc Royal Virginia Road Kells Co Meath Ireland	**EU Representative**
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	**ETO Sterilization** **Manufacture**
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	**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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	**Manufacture**
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	**Manufacture**
Master & Frank (Pinghu) Ent. Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Develompment Zone Zhejiang P.R. China	**Manufacture**

By Royal Charter

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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	**Manufacture**
O&M Halyard, Inc. 5405 Windward PKWY Alpharetta Georgia 3004 USA	**Regulatory Compliance**
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	**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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics S. de R. L. de C. V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Estado de México C.P. 54730 Mexico	**ETO Sterilization**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**Gamma Irradiation**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	**ETO Sterilization**
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**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 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Estate Moo 7, Tambol Donhuaroh Amphur Muang Chonburi 20000 Thailand	**Gamma Sterilization**
Synergy Sterilisation (M) Sdn Bhd Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 698961**

Date: **2019-02-25**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Date	Reference Number	Action
18 February 2019	9643055	First Issue.
Current	9643448	Traceable to NB 0086.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No: **FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

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Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No: **FM 544574**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of non-active digestive tract devices; non-active gynaecological devices, non-active regional anaesthesia devices, non-active respiratory devices, non-active surgical devices, non-active urology devices and active surgical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-03-09
Latest Revision Date: 2020-02-12

Effective Date: 2020-02-12
Expiry Date: 2023-02-11

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By Royal Charter

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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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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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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By Royal Charter

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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By Royal Charter

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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By Royal Charter

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**
Mediplast 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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By Royal Charter

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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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**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **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 Rüsch GmbH Willy-Rüsch-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 Rüsch, 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.

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.

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
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.

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
Current	3124053	Certificate renewal. Addition of supplementary product information table. Update to scope to include non-active sterile urology catheters. Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc 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 Rüsch GmbH. Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd. 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 Rüsch GmbH. Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C. Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

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Date	Reference Number	Action
	3124053	Addition of Degania Silicone Limited for Manufacture 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 Addition of Iotron Industries USA for E-beam Sterilization Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization.

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

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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