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

Digitally signed by Ghereg Victor
Date: 2024.05.07 10:33:54 EEST
Reason: MoldSign Signature
Location: Moldova

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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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

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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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**

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

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.

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By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 560441**

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

In respect of:

Spinostar Spinal Needles

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2010-06-02** Date: **2020-05-20** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 560441

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
190110-090190	SpinoStar Spinal Needles	Spinostar standard	For spinal anaesthesia and lumbar puncture.	Class III
190110-090220		Spinostar standard		Class III
190110-090250		Spinostar standard		Class III
190110-090270		Spinostar standard		Class III
190120-090220		Spinostar point pencil Opti		Class III
190120-090240		Spinostar point pencil Opti		Class III
190120-090250		Spinostar point pencil Opti		Class III
190120-090260		Spinostar point pencil Opti		Class III
190120-090270		Spinostar point pencil Opti		Class III
190120-105220		Spinostar point pencil Opti		Class III
190120-105240		Spinostar point pencil Opti		Class III
190120-105250		Spinostar point pencil Opti		Class III
190120-105260		Spinostar point pencil Opti		Class III
190120-105270		Spinostar point pencil Opti		Class III
190120-120220		Spinostar point pencil Opti		Class III
190120-120240		Spinostar point pencil Opti		Class III

First Issued: **2010-06-02** Date: **2020-05-20** Expiry Date: **2024-05-26**

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By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 560441

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
190120-120250	SpinoStar Spinal Needles	Spinostar point pencil Opti	For spinal anaesthesia and lumbar puncture.	Class III
190120-120260		Spinostar point pencil Opti		Class III
190120-120270		Spinostar point pencil Opti		Class III
190140-090220		Spinostar point Ball Pen		Class III
190140-090240		Spinostar point Ball Pen		Class III
190140-090251		Spinostar point Ball Pen		Class III
190140-090271		Spinostar point Ball Pen		Class III
190140-120250		Spinostar point Ball Pen		Class III
190140-120270		Spinostar point Ball Pen		Class III

First Issued: **2010-06-02** Date: **2020-05-20** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 560441

Issued To:

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

Certificate History

Date	Reference Number	Action
02 June 2010	10115462	First issue - Re-classification from IIa to III due to 2007/47/EC.
22 August 2012	10136981	Inclusion of full address.
27 June 2015	10155714	Certificate renewal. Removal of product codes from list: 190130-090250. 190130-090270. 190130-090290. 190130-127250. 190130-127270. 190130-127290. 190904-000250. 190904-000270.
21 September 2015	10149832	Change to Eto sterilisation cycle.
05 December 2016	10159837	Change to primary packaging material.
04 March 2019	7779566	Traceable to NB 0086.

First Issued: **2010-06-02** Date: **2020-05-20** Expiry Date: **2024-05-26**

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By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 560441

Issued To:

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

Date	Reference Number	Action
Current	3082796	Certificate renewal. Administrative update of supplementary product information table.

First Issued: **2010-06-02** Date: **2020-05-20** Expiry Date: **2024-05-26**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-03-09
Effective Date: 2023-02-12
Latest Revision Date: 2023-01-26
Expiry Date: 2026-02-11

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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 Number: 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 medical 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-12-09
Effective Date: 2023-01-09
Latest Revision Date: 2023-01-07
Expiry Date: 2026-01-08

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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. 1 Edison Drive Alpharetta Georgia 30005 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 medical 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, non-sterile face masks (respirators), 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. The manufacture of non-sterile face masks and respirators.
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: 2023-01-09

Latest Revision Date: 2023-01-07

Expiry Date: 2026-01-08

Certificate No: FM 697013

Location	Registered Activities
La Ada de Acuna Km. 4.5 Carretera 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 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 medical examination gloves.
La Ada de Acuna II Lote #8 del parque Industrial la Paz II Carretera Santa Eulalia #810 Cd. Acuña Coahuila C.P.26238 Mexico	Warehouse space for the storage of raw materials, components, and spare parts.
O&M Halyard Honduras S.A. de C.V. Carreterra Tegucigalpa Villanueva Building #7 Cortes Honduras	The manufacture and distribution of disposable non-sterile apparel and surgical gowns.

Original Registration Date: 2014-12-09

Effective Date: 2023-01-09

Latest Revision Date: 2023-01-07

Expiry Date: 2026-01-08

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 736225 R000

Manufacturer: Teleflex Medical

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Single Registration Number: Not Available

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-08-20** Date: **2021-08-20** Expiry Date: **2026-08-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 736225 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Intubation Device	Class Is
Bladder Catheter	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issued: **2021-08-20** Date: **2021-08-20** Expiry Date: **2026-08-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 736225 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-08-20	3290676	Issued.
2021-08-30	3290676	Amended - correction of the manufacturer address.

First Issued: **2021-08-20** Date: **2021-08-20** Expiry Date: **2026-08-19**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 736225 R000

Date: **2021-08-20**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	**Radiation (Gamma Sterilization)**
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist. 42944 Taichung City Taiwan	**Packaging**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 736225 R000

Date: **2021-08-20**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Teleflex Medical Sdn. Bhd. Lot PT 2577 Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**ETO Sterilization** **Packaging**

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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 15 July 2021 until 14 July 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 22. 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

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016

Issue 22

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

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