

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

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 24 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00

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

Certification is based on reports numbered WW/MC 06866

Authorised by

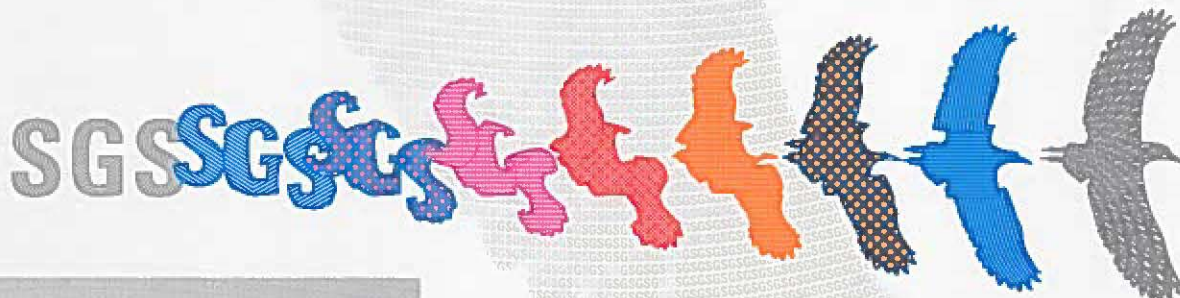


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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

**Sterile Hem-o-lok and Vesolock Ligation Clips,
Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesoclude
Metal Ligation Clips Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II,
"silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM
and 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 Applicators.
Metal Ligation System.**

**Sterile and Non-sterile External stapling system (including stainless steel staples,
staplers and removers), Sterile, Efx endo fascial closure system (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**



Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

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), 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.

Additional facilities

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



EC Certificate Production Quality Assurance System: Certificate US19/819943646.00

The management system of

SGS

Teleflex Medical

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

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

This certificate is valid from 01 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020

Certification is based on reports numbered WW/MC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US19/819943646.00

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

Authorised by



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Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Issue 1

Detailed scope

**Sterile Suture Guides, Sterile Belly Bags (Urine Collection Device),
Sterile stapler removers.**

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

Additional facilities

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





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



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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.

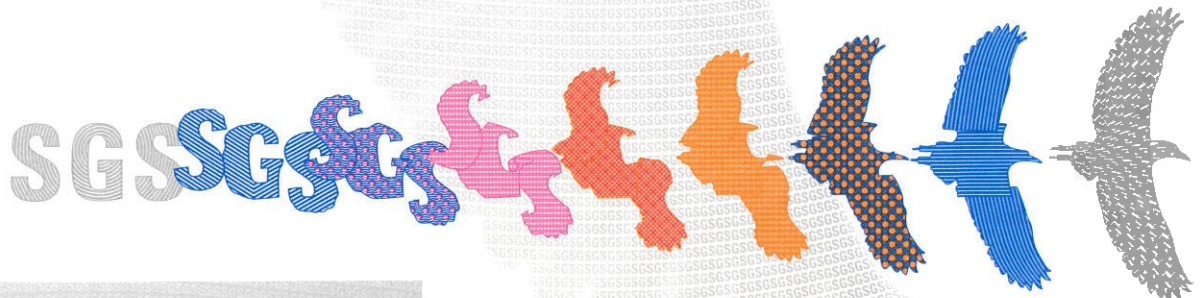
Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

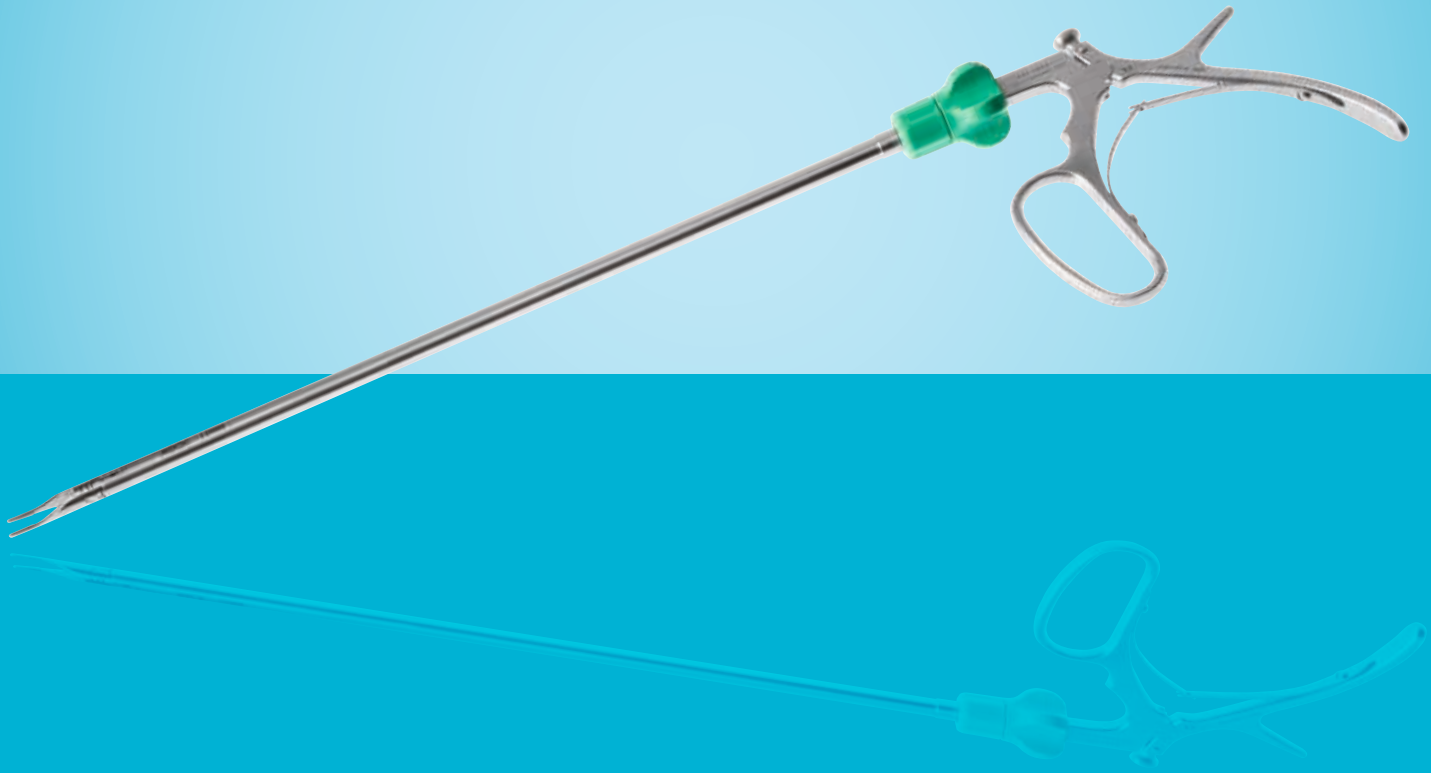
Additional facilities

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



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Weck
Horizon Ligation System
The Name You Know the Product You Trust





The Cartridge

Easy Loads with Adhesive Convenience

- The Horizon Clip Cartridge can provide easy and precise loading that can enhance surgical procedure efficiency.
- Lateral clip-restraining springs in the Horizon Cartridge are displaced by applier jaws during clip loading.
- Spring displacement frees the clip for a nearly frictionless one-hand load from the cartridge.
- Clips are centered in the cartridge slots for precise loads.
- Clip cartridges are colour-coded to match appliers.
- Both 6- and 24-clip cartridges are available.
- A special adhesive backing on the Horizon Cartridge allows the user to conveniently relocate the site of clip loading – cartridges affix to any sterile area.



The Appliers

Performance and Cleaning Accessibility

- The Horizon Endoscopic Applier provides clip closure designed to give surgeons solid tactile feedback.
- The large, lightweight rotation knob allows for one-finger, 360° rotation of the applier shaft.
- Horizon Endoscopic Appliers are available for medium, medium-large, and large Horizon Clips, and feature flush ports for thorough cleaning.
- The reusable appliers are designed specifically for use with Horizon Ligating Clips, which may save costs when compared to disposable automatic-feed clip appliers.
- All Horizon Open Surgical Ring-handled Appliers open at the box lock for easy, thorough cleaning.
- Open surgical appliers are available with angled, curved, or right-angled jaws.

Ligating Clips

Titanium Ligating Clips				
REF.	CLIP SIZE	CLIPS/CARTRIDGE	CARTRIDGES/BOX	CLIPS/BOX
005200	○ microclip	6	30	180
001200	● small	6	30	180
001204	● small	24	25	600
001201	● small-wide	6	30	180
001205	● small-wide	24	25	600
002200	● medium	6	30	180
002204	● medium	24	25	600
003200	● medium-large	6	20	120
003204	● medium-large	24	15	360
004200	● large	6	20	120
004204	● large	24	15	360

Open Surgery

Ligating Appliers			
REF.	CLIP SIZE	WORKING LENGTH	QTY
20° curved			
537061	○ microclip	6" (15 cm)	1
537081	○ microclip	8" (20 cm)	1
137061	● small	6" (15 cm)	1
137081	● small	8" (20 cm)	1
137111	● small	11" (28 cm)	1
137062	● small-wide	6" (15 cm)	1
137082	● small-wide	8" (20 cm)	1
137112	● small-wide	11" (28 cm)	1
237061	● medium	6" (15 cm)	1
237081	● medium	8" (20 cm)	1
237111	● medium	11" (28 cm)	1
337081	● medium-large	8" (20 cm)	1
337111	● medium-large	11" (28 cm)	1
437081	● large	8" (20 cm)	1
437111	● large	11" (28 cm)	1
55° angled			
137085	● small	8" (20 cm)	1
137086	● small-wide	8" (20 cm)	1
237085	● medium	8" (20 cm)	1
237115	● medium	11" (28 cm)	1
337085	● medium-large	8" (20 cm)	1
337115	● medium-large	11" (28 cm)	1
437085	● large	8" (20 cm)	1
437115	● large	11" (28 cm)	1
70° angled			
237117	● medium	11" (28 cm)	1
337117	● medium-large	11" (28 cm)	1
437117	● large	11" (28 cm)	1

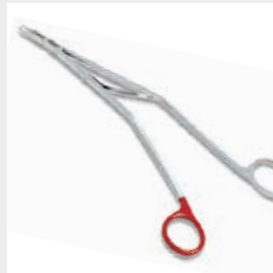
All Horizon Ligating Clips are packaged sterile. Ligating clip systems differ in their clip-closure characteristics. It is the responsibility of the user to confirm security of clips on vessels or other tissue. Not intended for contraceptive tubal occlusion.

Microclip Ligating Clip



The newest member of the Horizon System. For ligation of small vessels or structures.

Specialty Multi-Angle Appliers



The Horizon 28cm Multi-Angle Access Applier for small (wide slot) clip cartridges incorporates a 45° angled jaw, or a curved jaw, for an optimal angle of access to the surgical target.

Cross-sectional view of clip



With applier jaws properly aligned (above) and misaligned (below).

Endoscopic take-apart clip applier



Our TAP appliers can be taken apart for easy cleaning. They come with a 360° rotation knob for better access and improved visibility.

Open Surgery

Ligating Appliers, special

REF.	CLIP SIZE	APPLIER DESIGN	WORKING LENGTH	QTY
20° curved				
137118	● small-wide	multi-angled	11" (28 cm)	1
45° angled				
137117	● small-wide	multi-angled	11" (28 cm)	1

Endoscopic Surgery

Ligating Appliers, special

REF.	CLIP SIZE	Ø APPLIER	Ø TROCAR	WORKING LENGTH	QTY
238110T	● medium	10 mm	10 mm	13" (33 cm)	1
338110T	● medium-large	10 mm	10 mm	13" (33 cm)	1

Non-Take-apart ligating appliers

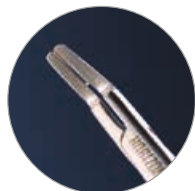
REF.	CLIP SIZE	Ø APPLIER	Ø TROCAR	WORKING LENGTH	QTY
438110	● large	12 mm	12 mm	11" (28 cm)	1

Non-Take-apart ligating appliers, endosaphenous

REF.	CLIP SIZE	Ø APPLIER	Ø TROCAR	WORKING LENGTH	QTY
238200	● medium	5 mm shaft, 7 mm jaw	8 mm	13" (32 cm)	1

The Horizon System: Designed to Meet Your Needs

The Horizon System is designed to meet the needs of surgeons, nurses, and other operating room personnel.



The Clip – functional excellence

- The chevron shape of the Horizon Clip engulfs tissue with precise tip-to-tip closure.
- The heart-shaped wire is designed to give each clip a firm grip on vessels.
- Transverse grooves make the Clip resistant to slipping across the vessel.
- The internal groove of the Horizon clip is sized to reduce clip scissoring.
- The triangulated cross-section of the Horizon clip leg maximises surface-to-surface contact of Clip and applier jaw, practically eliminating clip fallout.

□ Micro ■ Small ■ Small/Wide ■ Medium ■ Medium/Large ■ Large

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose-driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüsch, UroLift, and Weck – trusted brands united by a common sense of purpose.

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