

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 11 September 2018 until 14 July 2023  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 May 2021

Issue 30. Certified since 26 September 2000

Certification is based on reports numbered WWWMC/06866

Multiple certificates have been issued for this scope

The main certificate is numbered US97/10879.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

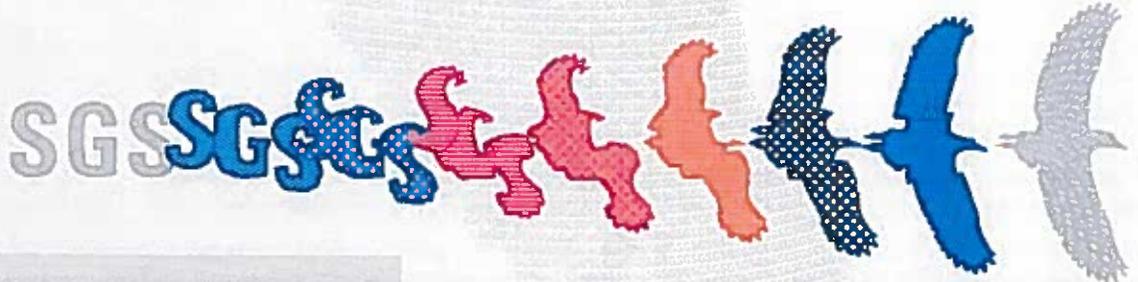
Authorised by

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SGS CE 02 0315 M2

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# Teleflex Medical

## Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 30

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 closure system (abdominal access), Sterile, Efx shield fascial closure system (abdominal access), Sterile, Efx classic fascial closure system (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

Additional facilities

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

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

