

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.

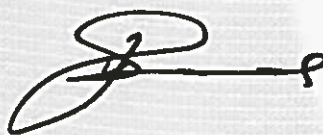
This certificate is valid from 25 January 2017 until 14 July 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 May 2018
Issue 26. Certified since 26 September 2000

Certification is based on reports numbered WW/MC 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 subsequent pages.

Authorised by



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Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
for class IIa, IIb & III

Issue 26

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®, Caplo™, 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), Percutaneous surgical System (Interchangeable
electrosurgical tool tips) for laparoscopic surgery.

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



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Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States
11245 N. Distribution Cove, Olive Branch, MS, 38654, United States
3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

