EC Certificate Full Quality Assurance System: Certificate US19/819943647.01

The management system of

Teleflex Medical

3015 Carrington Mill Blvd.
27560 Morrisville, 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 02 October 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. 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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Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Sterile Hem-o-lok and Vesolock Ligation Clips, Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesocclude 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 MONODEK® Polydioxanone Absorbable Surgical Sutures. Sterile Hem-o-lok Automatic Clip Appliers.nMetal 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 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), 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.