EC Certificate Full Quality Assurance System: Certificate US19/819943647.00



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

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

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

Page 1 of 3





This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_end_conditions.htm. Alterifon is drawn to the limitations of liability, indemnification and jurisdictional issues established herain. The authenticity of this document may be verified at https://www.sgs.com/ter/derified-clients-and-products/ostified-client-directory. Any unauthorized attention) tongery or faisification of the content or appearance of this document is unleaved and offenders may be prosecuted to the fullest extent of the law.



Teleflex Medical

Directive 93/42/EEC

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

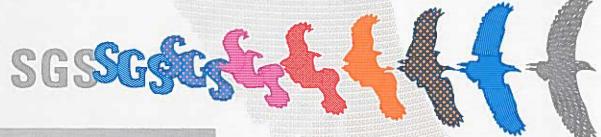
Issue 2

Detailed scope

Sterile Hem-o-lok and Vesolock Ligation Clips,
Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and 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 Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
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





This document is issued by the Compeny subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.ags.com/terms_and_conditions.htm. Attention is drawn to the limitations of Rability, indemnistation and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.ags.com/en/certified-clients-and-products/certified-clients-directory. Any unauthorized attention, forgery or falsification of the content or appearance of this document is unleavity and offenders may be prosecuted to the fullest extent of the law.

Page 2 of 3



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





This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.ags.com/lems_end_conditions.html / Attention is drawn to the limitations of Rebility, Indemnitication and jurisdictional issues established therein. The autherdicity of this document may be verified at https://www.ags.com/en/ourtiled-clients-end-products/certified-client-directory. Any unauthorized alteration forgery or fatelification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fulfact extent of the law.

EC Certificate Production Quality Assurance System: Certificate US19/819943646.00

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

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

Pieter Weterings Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

Page 1 of 2





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.ags.com/ferms. and conditions.htm. Attention is drawn to the first instance of labelity, intermellated and pursicional issues established therein. The authoritity of this document may be verified at http://www.ags.com/servicentied-clients-end-products/certified-client-directory. Any unauthorized attention, torger or featingstand of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest. Certificate US19/819943646.00, continued



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 lib or class ill medical device(s), a valid EC Type Examination Certificate according to Annex ill 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





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgx.com/herms_and_conditions.htm.
Attention is drawn to the irrelations of fability, indemnification and juriedictional issues established therein. The authenticity of this document may be verified at http://www.agx.com/ev/sertified-clients-and-products/certified-clients-and-products/certified-clients-fired-drawn.
Any unauthorized attention, longery or fatsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest certified in the content of th



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.

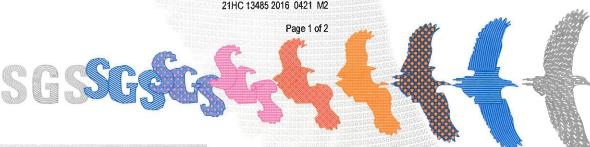
> > Authorised by



SGS United Kingdom Ltd Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

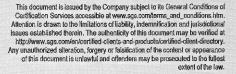
21HC 13485 2016 0421 M2













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











CERTIFICATE



This is to certify that the company

schülke -}-

Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

Scope:

Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07

EN ISO 13485 : 2016 + AC : 2016

ISO 13485: 2016

Certificate registration no. 004567 MP2016

Certificate unique ID 170774693

Effective date 2021-06-27

Expiry date 2024-06-26

Frankfurt am Main 2021-06-27

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

J. Mbleuc

Sigrid Uhlemann Managing Director Dr. Thomas Feldmann Head of Certification Body







Annex to certificate

Certificate registration No.: 004567 MP2016

Certificate unique ID: 170774693

Effective date: 2021-06-27

Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

0	c	а	T	ı	റ	n

Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

Schülke & Mayr AG

Sihlfeldstrasse 58 8003 Zürich Switzerland

Schülke & Mayr Ges. m. b. H.

Seidengasse 9 1070 Wien Austria

Schülke France S.A.R.L.

50 boulevard National 92250 La Garenne France

Schülke & Mayr UK Ltd.

Cygnet House, 1 Jenkin Road, Meadowhall Sheffield, S9 1AT United Kingdom

Schülke & Mayr Benelux B.V.

Oudeweg 8d 2031 CC Haarlem Netherlands

Schulke Polska Sp. z o.o.

Eurocentrum Office Complex Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland

Scope

Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

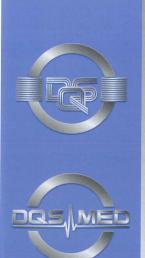
Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.





EC-CERTIFICATE



(Full quality assurance system)

This is to certify that the company



Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectant for medical devices, wound care products and gel as listed in annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 004567 MR2
Certificate unique ID 170742365
Effective date 2020-06-09
Expiry date 2023-12-18
Frankfurt am Main 2020-06-09

DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director

Dr. Thomas Feldmann Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de





Annex to certificate

Certificate registration No.: 004567 MR2

Certificate unique ID: 170742365

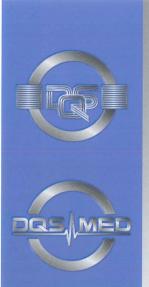
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

Device	Class
acryl-des® Gebrauchslösung	lla
acryl-des® Desinfektionstücher	lla
antifect® AF (N)	lla
antifect® N liquid	lla
antifect® extra	lla
aspirmatic®	lla
boots wound healing gel	IIb
dentavon®	lla
dentavon® liquid	lla
Essential+ Wipes	lla
gigasept® AF	IIb
gigasept® AF forte	IIb
gigasept® FF (neu)	IIb
gigasept® Instru AF	IIb IIb
gigasept® med	IIb
gigasept® pearls	IIb
gigasonic®	IIb
gigazyme® Xtra mikrozid® AF liquid	lla
mikrozid® AF iliquid mikrozid® AF wipes	lla
mikrozid® alcohol free liquid	lla
mikrozid® alcohol free wipes jumbo	lla
mikrozid® liquid	lla
mikrozid® PAA wipes	IIb
mikrozid® sensitive liquid	lla
mikrozid® sensitive wipes	lla
mikrozid® universal liquid	lla
mikrozid® universal wipes	lla
mikrozid® wipes	lla
mucalgin®	lla
mucadont® IS	IIb
mucapur® CD	lla
mucocit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	lla
octenisept® Gel	IIb
octenisept® wound gel	IIb





Annex to certificate

Certificate registration No.: 004567 MR2

Certificate unique ID: 170742365

Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2 22851 Norderstedt Germany

Device	Class
perform®	lla
pursept® AF	lla
pursept® A Xpress liquid	lla
pursept® A Xpress wipes	lla
quartamon® med	lla
rotasept®	IIb
septinol® SA	lla
terralin® liquid	lla
terralin® protect	lla
thermosept® ED	IIb
thermosept® NDR	lla
TPH® protect	lla
SteraClar Daily	lla
SteraDif Powder	lla
SteraPex	IIb
SteraPex Rotary	IIb
SteraClens Alcohol Free	lla
SteraClens	lla
SteriWipe+ Alcohol Free	lla
SteriWipe+	lla
DESIMATIC-ID PLUS	IIb
DESIFOR-ONE multi wipes	lla
DESIFOR-ONE PROTECT	lla
B3	lla

