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

Digitally signed by Dubalari Pavel
Date: 2022.11.24 10:48:33 EET
Reason: MoldSign Signature
Location: Moldova

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

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**

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

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

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

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

UKAS MANAGEMENT SYSTEMS
0005

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

UKAS MANAGEMENT SYSTEMS
0005

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 698961**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

In respect of:

The manufacture of Surgical Drapes.

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile surgical gowns, surgical drapes, surgical packs and examination gloves

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 698961

Issued To:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD 0101	Transurethral Resection (T.U.R.) Drapes & Packs	N/A
Class Is		
MDS7006	Surgical Gowns	N/A
MDS7006	Surgical Drapes	N/A
MDS7006	Surgical Packs	N/A
MDS7006	Examination Gloves	N/A

First Issued: **2019-02-18** Date: **2019-02-25** Expiry Date: **2024-02-17**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Arc Royal Virginia Road Kells Co Meath Ireland	**EU Representative**
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	**ETO Sterilization** **Manufacture**
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	**Manufacture**
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	**Manufacture**
Master & Frank (Pinghu) Ent. Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Develompment Zone Zhejiang P.R. China	**Manufacture**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	**Manufacture**
O&M Halyard, Inc. 5405 Windward PKWY Alpharetta Georgia 3004 USA	**Regulatory Compliance**
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	**Manufacture**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics S. de R. L. de C. V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Estado de México C.P. 54730 Mexico	**ETO Sterilization**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**Gamma Irradiation**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	**ETO Sterilization**
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 698961**
Date:	**2019-02-25**
Issued To:	**O & M Halyard, Inc.** **9120 Lockwood Blvd** **Mechanicsville** **Virginia** **23116** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Estate Moo 7, Tambol Donhuaroh Amphur Muang Chonburi 20000 Thailand	**Gamma Sterilization**
Synergy Sterilisation (M) Sdn Bhd Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**Gamma Sterilization**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 698961**

Date: **2019-02-25**

Issued To: **O & M Halyard, Inc.**
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Date	Reference Number	Action
18 February 2019	9643055	First Issue.
Current	9643448	Traceable to NB 0086.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No: **FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

...making excellence a habit.™

Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

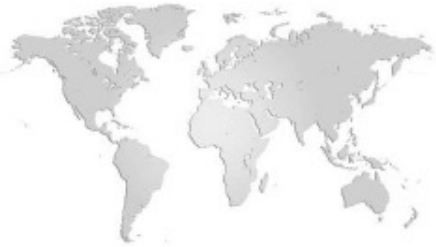
Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15 *

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system

DEKRA Certification GmbH * Stuttgart, Handwerkstraße 15 * D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.
Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization).

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-Z7-00.

Certificate registration no.:	50593-14-01	Certificate valid from:	2020-04-01
Validity of previous certificate:	2020-03-31	Certificate valid to:	2023-03-31

DEKRA Certification GmbH * Stuttgart, Handwerkstraße 15 * D-70565

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

Annex to the Certificate No. 50593-14-01

Revision status: 0

valid from 2020-04-01 to 2023-03-31

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	See page 1
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Deutschland	Manufacture of flexible and rigid endoscopes

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2024-05-27**

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB410200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB410200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®
Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB410200310

List of products / product categories included in the scope of certificate

Medical devices for Urology

- **Biopsy guns**
- **Catheters**
- **Catheter sets**
- **Guide wires**
- **Stone retrieval baskets**
- **Cannulas**
- **Dilators**
- **Ureteral stents**

– End of list –

MEDCERT®
Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2024-05-27**

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB415200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED/CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB415200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1202
Certificate No.: 1202GB415200310

List of products / product categories included in the scope of certificate

Medical devices for Urology

- **Catheters**
- **Catheter accessories**
- **Urine-drainage systems**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®

Certification. Medical Only.

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection and distribution of medical devices for

- **Urology**
- **Gynecology**
- **Radiology**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-12**
Expiry date: **2023-03-12**

Report No.: 1202FS27F
Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

Appendix of certificate

Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-19630-04-00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 075182 0006 Rev. 00

Manufacturer:
PULSION Medical Systems SE
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies):
PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Product Category(ies):
Patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713153619

Valid from: 2019-05-17
Valid until: 2023-05-24

Date, 2019-05-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

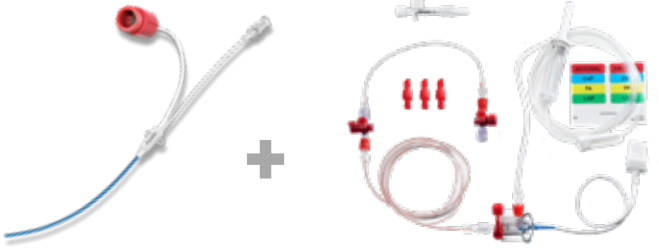
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Lot :198

3.5 PiCCO Kits

PiCCO Kits consists of:

PiCCO Catheter + **Monitoring Kit**



Additional information about the PiCCO Catheter see chapter 3.1; page 11

Additional information about the Monitoring Kits see chapter 3.2; page 12

PiCCO Catheter	Monitoring Kit	REF	Getinge order #
PV2015L20-A **6885049** Ø: 5 French Usable length: 20 cm	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2015L20-A 5 pieces	6885060 1 purchase unit
PV2013L07-A **6885044** Ø: 3 French Usable length: 7 cm	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2013L07-A 5 pieces	6885055 1 purchase unit
PV2014L08-A **6885045** Ø: 4 French Usable length: 8 cm	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2014L08-A 5 pieces	6885056 1 purchase unit
PV2014L16-A **6885046** Ø: 4 French Usable length: 16 cm	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2014L16-A 5 pieces	6885057 1 purchase unit
PV2014L22-A **6885047** Ø: 4 French Usable length: 22 cm	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2014L22-A 5 pieces	6885058 1 purchase unit

Suction-Irrigation Tube Sets

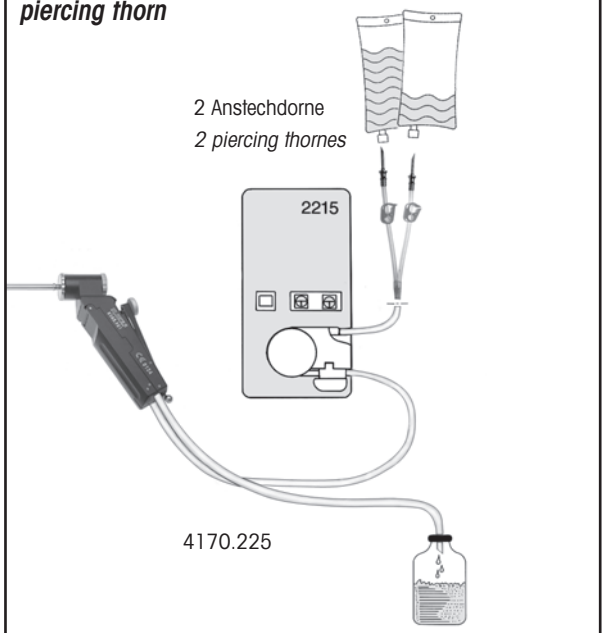
Saug-Spül-Schlauchsets

Disposable

Einmalgebrauch

Anstechdorn
piercing thorn

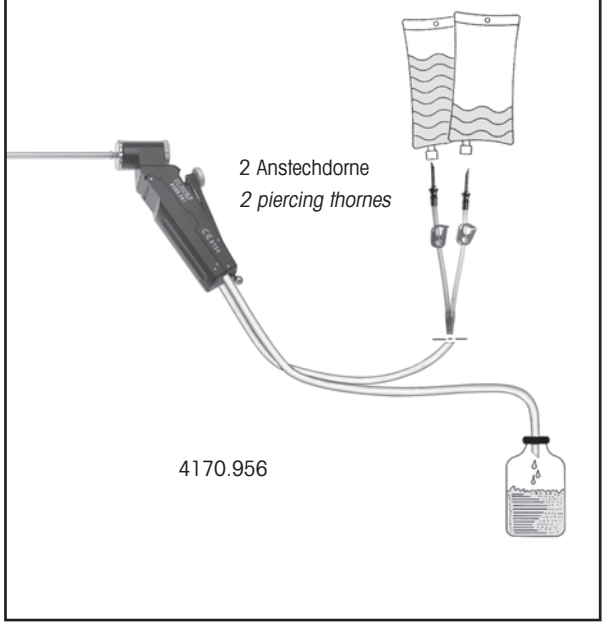
2215



Schlauchset
PVC, mit 2 Anstechdornen
Einmalartikel
VE = 10 Stück, einzeln steril verpackt 4170.225

Tube set
PVC, with 2 piercing thorns
disposable
Pack of 10, packed singly, sterile 4170.225

Anstechdorn
piercing thorn



Saug-Spül-Schlauchset,
mit 2 Anstechdorne,
VE = 10 Stück, einzeln steril verpackt 4170.956

Suction-irrigation tube set,
with 2 piercing thorns
Pack of 10, packed singly, sterile 4170.956

Declaration of Conformity

Declares under our sole responsibility that the product to which this declaration relates is in conformity with the provisions of Council Directive 93/42/EEC (Medical Device Directive, MDD).

Manufacturer & address

PULSION Medical Systems SE
Hans-Riedl-Str. 17
85622 Feldkirchen
Germany

Product Name	PiCCO Catheter
Product Model Number	PV2015L20-A, PV2014L22-A, PV2013L07-A, PV2014L08-A, PV2014L16-A, PV2014L50-A
Device Classification	IIa according Annex IX, Rule 7.
GMDN Code	10689, Arterial blood pressure catheter

PULSION Medical Systems SE is assessed to
EN ISO 13485:2016 and MDD Annex II excluding section (4) by the following Notified Body:

DEKRA Certification GmbH
Handwerkstraße 15
70565 Stuttgart
Germany

Identification Number 0124

This declaration of conformity is valid in combination with the following certificates or until the next substantial change of the product:

- **the EC Certificate No. 50215-16-08**
  (expiration date 24 May. 2023**)**

PULSION Medical Systems SE
Feldkirchen, 30 May. 2018

Jens Anter
Head of Quality Management & Regulatory Affairs

Stephan Haft
Managing Director