

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	Product Name	PiCCO Catheter
PULSION Medical Systems SE Hans-Riedl-Str. 17 85622 Feldkirchen Germany	Product Model Number	PV2015L20-A, PV2014L22-A, PV2013L07-A, PV2014L08-A, PV2014L16-A, PV2014L50-A
	Device Classification	Ila according Annex IX, Rule 7.
	GMDN Code	10689, Arterial blood pressure catheter

PULSION Medical Systems SE is assessed to

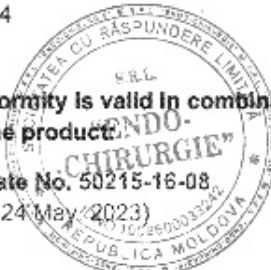
EN ISO 13485:2016 and MDD Annex II excluding section (4) by the following Notified Body:

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-B5-244.10.08



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



Product Service

Certificate

No. Q5 075182 0005 Rev. 00

Holder of Certificate: **PULSION Medical Systems SE**

Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies):

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

Certification Mark:



Scope of Certificate:

Design and development, manufacturing, packaging, marketing, sales and servicing of patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713153619

Valid from:

2019-05-17

Valid until:

2021-05-24



S. Preiß

Date, 2019-05-17

Stefan Preiß

CERTIFICATE

Number: 2238851

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Richard Wolf GmbH

Pforzheimer Str. 32
75438 Knittlingen
Germany

Manufacturer DUNS 315304071

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

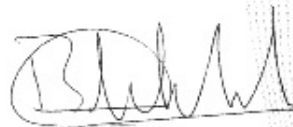
Scope:

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).

Certificate expiry date: 2022-07-01
Certificate effective date: 2019-07-11
Certified since: 2019-07-11

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2238851

The management system of the organization(s) and/or location(s) of:

Richard Wolf GmbH

Pforzheimer Str. 32
75438 Knittlingen
Germany

Certified organization(s) and/or locations:

Different scope

Richard Wolf GmbH
Reuchlinstr. 10-11
10553 Berlin
Germany
DUNS 315079765

Manufacture of flexible and rigid endoscopes.

Addendum expiry date:

Addendum effective date:





By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 540595

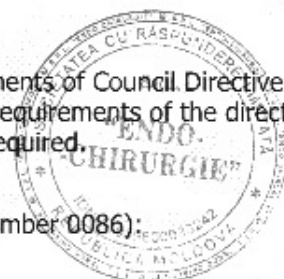
Issued To:

**Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland**

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.



For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 January 2009**

Date: **28 August 2015**

Expiry Date: **07 September 2020**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Arrow International CR, a.s. Jamska 2359/47 59101 Zdar nad Sazavou Czech Republic	Control of Sterilization Design Manufacture
Arrow International CR, a.s. Prazska 209 50004 Hradec Kralove Czech Republic	Control of Sterilization Design Manufacture
Arrow Medical Ltd Hatton Gardens Industrial Estate Kington HR5 3RB United Kingdom	Crucial Supplier
CeMed GmbH Oberdorf 41 72419 Neufra Germany	Control of Sterilization Manufacture



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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Chelle Medical Limited PO Box 221 Le Rocher Victoria Mahe Seychelles	Crucial Supplier
Forefront (Xiamen) Medical Devices Co., Ltd No 26 & 28 Haijing Dong Lu Haicang Xiamen Export Processing Zone 361026, Xiamen, Fujian China	Crucial Supplier
Forefront Medical Technology Pte Ltd 35 Joo Koon Circle, 6th Floor Singapore 629110 Singapore	Crucial Supplier



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EC Certificate - Full Quality Assurance System

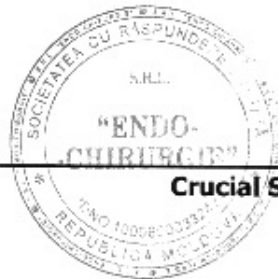
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	Crucial Supplier
Parker Medical Systems Division - Merrillville 1201 East 86th Place Merrillville Indiana 46410 USA	Crucial Supplier
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas 30020 Ipoh Perak Malaysia	Crucial Supplier



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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
SP Medical A/S Møllevej 1 4653 Karise Denmark	Control of Sterilization Design Manufacture
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	Control of Sterilization Manufacture
Teleflex Medical Sdn. Bhd. Lot PT2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	Control of Sterilization Design Manufacture
Teleflex Medical Asia Pte. Ltd. 6 Battery Road #07-02 049909 Singapore	Control of Sterilization Design Manufacture



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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park, Kulim 09000 Malaysia	Crucial Supplier
Tianjin Medis Medical Device Co. Ltd 10A Tianzhi Industrial Centre No 12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin City China	Control of Sterilization Manufacture
Willy Rüsç GmbH Willy Rüsç-Strasse 4-10 D-71394 Kernern Germany	Control of Sterilization Design Manufacture



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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüscher, Germany as subcontractor for design and manufacture
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors



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Page 1 of 2

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd
09 March 2015	8293488	Addition of 8 crucial suppliers
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.



CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

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-Z6U1-00.

This certificate is valid from 2019-04-01 to 2020-05-16

Registration No.: 50593-14-00

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-04-01



Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

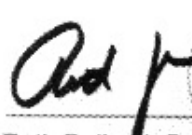
Annex to the Certificate No. 50593-14-00

Revision status: 0

valid from 2019-04-01 to 2020-05-16

The following locations belong to the certificate above:

Headquarters	Certified location	Scope of certification
Richard Wolf GmbH	Pforzheimer Straße 32 D-75438 Knittlingen, Germany	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)
Subsidiaries	Certified locations	Scope of certification
1. Richard Wolf GmbH	Reuchlinstraße 10-11 D-10553 Berlin, Germany	Manufacture of flexible and rigid endoscopes


Ruth Delbeck-Bayer



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-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-16-04

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-05-17
Notified Body ID-number: 0124



Benutzt durch/Designated by
Zentraltabelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50593-16-04

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

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.

- Suction system filter, plume particulate

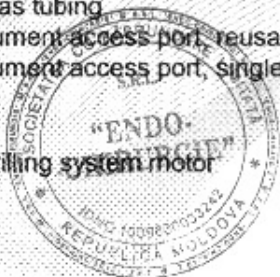
Class I m:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- Robotic surgical navigation system application software

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone punch
- Bronchoscopy tube
- Cannulated surgical drill, reusable
- Endoscope assembly adaptor
- Endoscope leak tester, mechanical
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic irrigation/aspiration pump
- Endoscopic needle, general-purpose, reusable
- ENT probe
- Flexible fiberoptic bronchoscope
- Flexible fiberoptic choledochoscope
- Flexible fiberoptic cystourethroscope
- Flexible fiberoptic hysteroscope
- Flexible fiberoptic nasopharyngoscope
- Flexible fiberoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope
- Fluted surgical drill, reusable
- Fluted surgical drill, single use, sterile
- General-purpose suction system, line-powered
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laparoscopic sleeve
- Laser lithotripsy system
- Line-powered surgical drilling system motor



Annex to the EC Certificate No. 50593-16-04

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class II a:

- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic burr, reusable
- Orthopaedic burr, single use
- Oscillating surgical saw blade, reusable
- Oscillating surgical saw blade, single use
- Particulate water purification filter
- Proctoscope, reusable
- Rectoscope
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscopic cannula, reusable
- Rigid endoscopic cannula, single use
- Rigid endoscopic grasping forceps, reusable
- Rigid endoscope sheath
- Rigid endoscope telescope
- Rigid endoscope working guide
- Rigid hysteroscope
- Rigid intubation laryngoscope
- Rigid mediastinoscope
- Rigid nephroscope
- Rigid oesophagoscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Rigid video laparoscope
- Sagittal surgical saw blade, reusable
- Sagittal surgical saw blade, single use
- Self-retaining surgical retraction system ring
- Spring-loaded pneumoperitoneum needle, reusable
- Stereotactic surgery system probe, reusable
- Suction cannula, reusable
- Suction system tubing
- Surgical drill chuck
- Surgical fluid/smoke waste management system suction unit
- Surgical gouge
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical irrigation tubing set, single-use
- Surgical power tool system control unit, line-powered
- Surgical power tool system handpiece, rotary, pneumatic
- Surgical utensil washer/decontaminator
- Tissue extraction bag
- Tissue morcellation system
- Uterine manipulator

Annex to the EC Certificate No. 50593-16-04

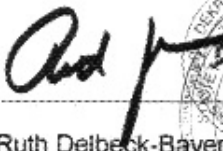
Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class II b:

- Clip, surgical, suture
- Electrohydraulic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system
- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, single-use
- Endoscopic electrosurgical 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
- Gastrointestinal endoscopic insufflator
- Hysteroscopic irrigation/insufflation system
- Laser lithotripsy system
- Nasal snare, reusable
- Operating room audiovisual data/device management system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Polymeric ureteral stent
- Ultrasonic lithotripsy system
- Ureteral stent-placement set


Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2017-05-17
Notified Body ID-number: 0124



EC CERTIFICATE

for the Quality Assurance System



**according the Directive 93/42/EEC,
Annex V**

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 V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-17-03

Ruth Delbeck-Bayer

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart, 2017-05-17
Notified Body ID-number: 0124



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

Annex to the EC Certificate No. 50593-17-03

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

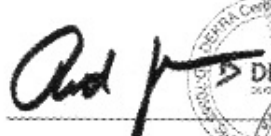
Class I s:

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

- Endoscope assembly adaptor
- Endoscope inflation bulb
- Flexible bronchoscopic biopsy forceps, reusable
- Flexible endoscopic cytology brush, single-use
- General-purpose ureteral catheter
- Proctoscope, single-use
- Rigid endoscope sheath
- Ureteropelvic balloon catheter
- Urinary stone retrieval basket, single-use

Class II a:

- Catheter introducer
- Endoscopic antifog solution
- Endoscopic needle, general-purpose, single-use
- Flexible bronchoscopic biopsy forceps, reusable
- General-purpose non-vascular guidewire


Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-05-17
Notified Body ID-number: 0124



CERTIFICATE



ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the company

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, sales, installation and service of systems, active medical devices (sterile, non sterile), non-active medical devices (sterile, non sterile), non-active implants, accessories for processing (cleaning, disinfection, sterilization, care) as well as endoscopes and accessories for industrial applications.

Certified location:

D-75438 Knittlingen, Pforzheimer Straße 32

Scope of certification:

Production of rigid endoscopes

Certified location:

D-10553 Berlin, Reuchlinstr. 10-11

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A18071064.

This certificate is valid from 2018-09-12 to 2020-05-16

Certificate registration no.: 90714422/2

Lothar Weinofen
Lothar Weinofen

DEKRA Certification GmbH Stuttgart, 2018-09-12



Deutsche
Akkreditierungsstelle
D-ZM-16029-G1-01

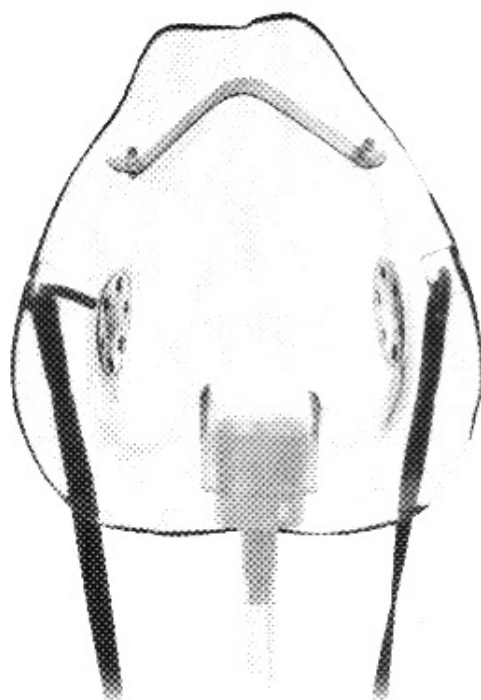
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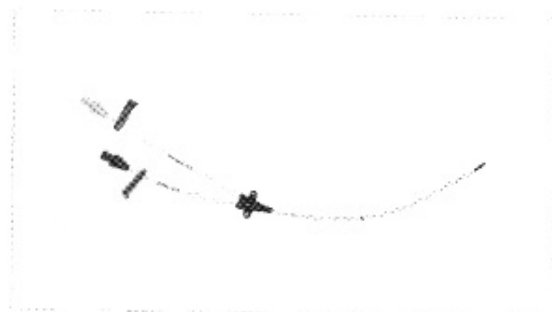


Details:

MEDIUM-CONCENTRATION MASKS

- Clear, soft vinyl for patient comfort and visual assessment
- Adjustable nose clip assures comfortable fit
- Complete with 210cm Star Lumen® Oxygen Supply Tubing





Representative photo(s): actual product specifications may vary from that shown in the photo

7 Fr x 20 cm Two-Lumen Central Venous Catheterization Set with Blue FlexTip® ARROWg+Ard-Blue® Catheter

CVC SET: 2-LUMEN 7FR X 20CM

SKU / Article #: EU-27702-CVT

Highlights

CE Mark

Contraindications & Considerations

Not made with natural rubber latex.

Sales Quantity/Case: 10

7 Fr x 20 cm Two-Lumen Central Venous Catheterization Set with Blue FlexTip® ARROWg+Ard-Blue® Catheter

SKU / Article #: EU-27702-CVT

Quantity	Component Description
1	Two-Lumen Indwelling Catheter: 7 Fr. x 20 cm Radiopaque Polyurethane with Blue FlexTip®, ARROWg+ard® Antimicrobial Surface Treatment ¹ , Extension Line Clamps
1	Spring-Wire Guide, Marked: .032" (0.81 mm) dia. x 23-5/8" (60 cm) (Straight Soft Tip on One End - "J" Tip on Other) with Arrow Advancer with ECG Mark
1	Introducer Needle: Echogenic 18 Ga. x 2-1/2" (6.35 cm) XTW
1	Syringe: 5 mL Luer-Slip
1	Tissue Dilator: 8.5 Fr. (2.8 mm) x 10.2 cm
1	ECG Extension Cable
1	Injection Site Cap
1	SecondSite™ Adjustable Hub: Fastener
1	SecondSite™ Adjustable Hub: Catheter Clamp
1	SecondSite™ Adjustable Hub: Fastener

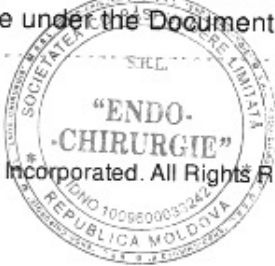


Documents



The products in this catalog may not be available in all countries. Please contact your local representative.

Indications, contraindications, warnings and instructions for use can be found in the Product Instructions for Use available under the Documents section on this page, where an IFU is available.



Dimensions:
Width: 6-3/4" (17.2 cm)
Length: 12-5/16" (28.7 cm)

PV2015L20-A

Ø 5 French
Usable length: 20cm

PV8215

Pressure transducer & 150cm arterial pressure line
Aortic sensor housing (PV4046)

PVPK2015L20 A

5 pieces

6885060

1 purchase unit



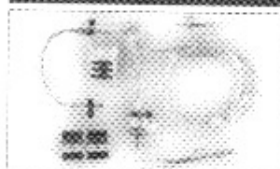
2.2 PICCO® - Monitoring Kit

Product description

PULSION article #

MAQUET order #

Purchase quantity



Monitoring Kit

Included Monitoring Kit components:

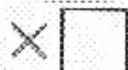
Arterial pressure transducer, injectate temperature sensor housing (PV4046), 30cm
arterial pressure line red marked

PV8203

5 pieces

6882815

1 purchase unit



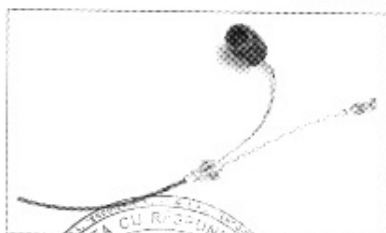
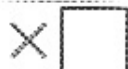
Arterial pressure transducer, injectate temperature sensor housing (PV4046), 150cm
arterial pressure line red marked

PV8215

5 pieces

6882817

1 purchase unit



Disposable
PICCO® - Catheters
with Trogamid Luer
connector and Nitinol
Guidewire

Recommended for use with approach as listed below:

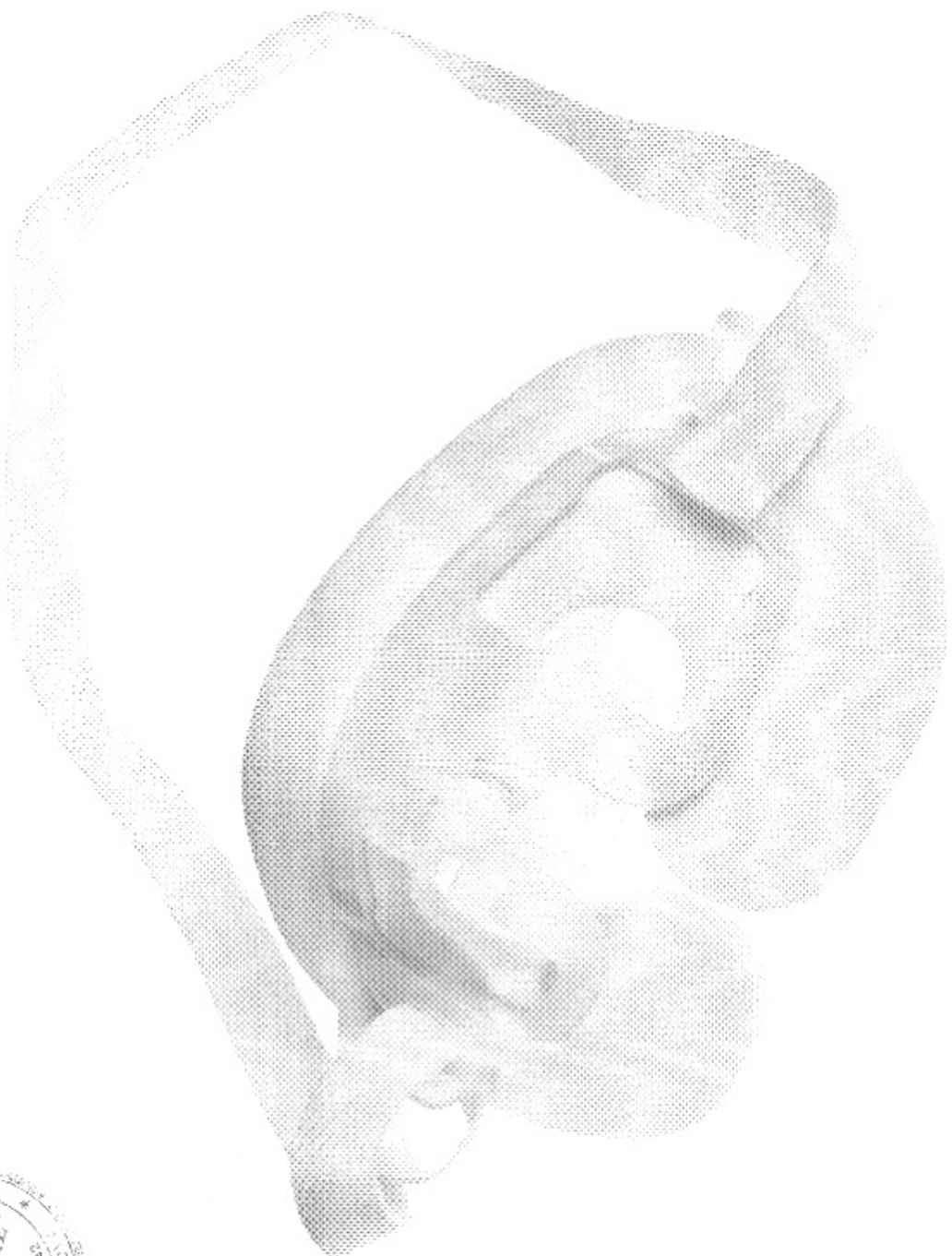
PICCO® Catheter with Trogamid Luer connector and
Nitinol Guidewire for femoral artery in adults
(standard catheter)

Ø 5 French
usable length:
7.78 in (20 cm)

PV2015L20-A
5 pieces



ДЕРЖАТЕЛЬ ЭНДОТРАХЕАЛЬНОЙ ТРУБКИ		
КОД	ОПИСАНИЕ	
41065	• Удерживает эндотрахеальную трубку на месте • Поставляется с матерчатой тесьмой, предохранителем и прокладкой для рта из мягкой пены • Встроенный прикусной блок	



T-TUBES

RÜSCH GOLD® T-TUBE, KEHR TYPE made of Silkolatex

- without funnel
- sterile, double-packed

T-TUBE, KEHR TYPE made of soft rubber

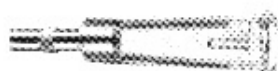
- without funnel
- sterile, double-packed

RÜSCH GOLD® T-TUBE

REF.	ORDER SIZE (O.D.) MM					LENGTH	QTY
178700*	3.0	3.5	4.0	4.5	5.0	50 x 16 cm	10
	5.5	6.0	7.0	8.0			
178900*	3.5	4.0	4.5	5.0	5.5	70 x 16 cm	10
	6.0	7.0	8.0				

T-TUBE

REF.	ORDER SIZE (O.D.) MM						LENGTH	QTY
423600*	2.5	3.0	3.5	4.0	4.5	5.0	70 x 16 cm	10
	5.5	6.0	7.0	8.0	9.0	10.0		
423601*	3.0	4.0	5.0	6.0			70 x 16 cm	5
	open gutter cross bar							



DETACHABLE FUNNEL made of PVC

- for T-Tubes
- sterile

DETACHABLE FUNNEL

REF.	ORDER SIZE FUNNEL SIZES (O.D.)	IN COMBINATION WITH T-TUBE MADE OF SILKOLATEX REF. 178700* / 178900*	IN COMBINATION WITH T-TUBE MADE OF SOFT RUBBER REF. 423600* / 423601*	QTY
333169	1.8 mm	O.D. 3.0 mm	O.D. 2.5 - 3.0 mm	10
	2.5 mm	O.D. 3.5 - 4.0 mm	O.D. 3.5 - 4.0 mm	
	3.0 mm		O.D. 4.5 mm	
	3.5 mm	O.D. 4.5 - 5.0 mm	O.D. 5.0 mm	
	4.0 mm		O.D. 5.5 - 6.0 mm	
	4.5 mm	O.D. 5.5 - 6.0 mm	O.D. 6.5 mm	
	5.0 mm		O.D. 7.0 mm	
	5.5 mm	O.D. 7.0 - 8.0 mm	O.D. 8.0 / 9.0 / 10.0 mm	

* These products contain natural rubber latex which may cause allergic reactions.

S.C. "Endo-Chirurgie" S.R.L.
Codul fiscal: 1009600033242
Adresa postală: mun.Chișinău, str.Mesterul Manole nr.9
Telefon/Fax: (022) 23-21-33, (022) 66-72-86



Nr. de ieșire: 19/04 din 17.04.2020

Către: IMSP SCM Sf. Treime,
mun. Chișinău, str. Alecu Russo, nr. 11/1, MD-2068.
Licitația Nr.: ocds-b3wdp1-MD-1583498963063/21020907,
"Achiziționarea consumabilelor parafarmaceutice".

DECLARAȚIE

Prin prezenta, SRL "Endo-Chirurgie" declară următoarele:

Se obligă să prezinte la solicitarea autorității contractante/beneficiarului,
mostre în decurs de 3 zile de la solicitare.

Cu respect,

Director



Victor GHEREG