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

TÜV SÜD 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. 01

Manufacturer:

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.: 713169773

Valid from: 2020-03-11
Valid until: 2024-05-26

Date, 2020-03-11

Christoph Dicks
Head of Certification/Notified Body

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-R2-00.

Certificate registration no.:	50593-14-02	Certificate valid from:	2021-11-29
Validity of previous certificate:	2021-11-28	Certificate valid to:	2024-11-28

DEKRA Certification GmbH * Stuttgart * Handwerkstraße 15

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

Annex to the Certificate No. 50593-14-02

Revision status: 0

valid from 2021-11-29 to 2024-11-28

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Germany	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 Germany	Manufacture of flexible and rigid endoscopes

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

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 Stuttgart, Handwerkstraße 15 • D-70565

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

34460

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 D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
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-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.: 50593-17-04

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

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

84460

Annex to the EC Certificate No. 50593-17-04

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.

- Endoscope inflation bulb
- Proctoscope, single-use
- Rectoscope, single-use

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

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

GETINGE

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	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 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) by the following Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

Identification Number 0123

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. G1 075182 0006**
  (expiration date 26 May. 2024)

PULSION Medical Systems SE
Feldkirchen, 17 Jun. 2020

Jens Anter
Head of Quality Management & Regulatory Affairs

Stephan Haft
Managing Director

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

Phone: +49 89 4599 14 0
Email: info@pulsion.com
www.getinge.com

GETINGE

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 Monitoring Kit
	Product Model Number	PV8215, PV8215-2, PV8203, PV8215CVP, PV8615
	Device Classification	IIa according Annex IX, Rule 10
	GMDN Code	45275, Blood pressure transducer set

PULSION Medical Systems SE is assessed to

EN ISO 13485:2016 and Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) by the following Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

Identification Number 0123

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

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  (expiration date 26 May. 2024)

PULSION Medical Systems SE
Feldkirchen, 17 Jun. 2020

Jens Anter
Head of Quality Management & Regulatory Affairs

Stephan Haft
Managing Director

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85622 Feldkirchen
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Email: info@pulsion.com
www.getinge.com

GETINGE

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**	Injectate Temperature Sensor Housing
	Product Model Number	PV4046
	Device Classification	IIa according Annex IX, Rule 2
	GMDN Code	10615, Thermal-dilution cardiac output unit

PULSION Medical Systems SE is assessed to

EN ISO 13485:2016 and Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) by the following Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

Identification Number 0123

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. G1 075182 0006**
  (expiration date 26 May. 2024)

PULSION Medical Systems SE
Feldkirchen, 17 Jun. 2020

Jens Anter
Head of Quality Management &
Regulatory Affairs

Stephan Haft
Managing Director

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www.getinge.com

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

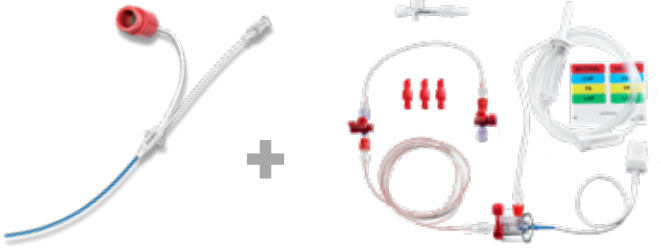
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
			PV2015L20-A						
DM000305561	CATETER PENTRU MĂSURAREA PRESIUNII ARTERIALE	PiCCO	PV2015L20-A		Germania	PULSION MEDICAL SYSTEMS SE	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000084	14-04-2021

Lot :31

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