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ZERTIFIKAT ◆ **CERTIFICATE** ◆ 認證書 ◆ **CERTIFICADO** ◆ **CERTIFICAT**

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 2020-04-06 15:55 by Jenni Ritter u4000772



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
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 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. 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

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 Module
	Product Model Number	PC4510
	Device Classification	IIb according Annex IX, Rule 10
	GMDN Code	36561, Patient monitoring system module, cardiac output

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

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



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



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



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DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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








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



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Lot : 128



Order data	
	<p>Power Stick M5/3 Motor handpiece for driving rotation tools, with three function keys</p> <p>with fixed connection cable, 3.0 m 8995500031 with removable connection cable, 3.0 m 89955.0003</p>
	<p>Power Stick M5/0 Motor handpiece for driving rotation tools,</p> <p>with fixed connection cable, 3.0 m 8995500001 with removable connection cable, 3.0 m 89955.0000</p>
	<p>Micro Stick S1 Motor handpiece for driving rotation tools, with one function key</p> <p>with fixed connection cable, 3.0 m 89951.0001</p>
	<p>PowerSpeed AS1 generator 2305 Universal motor system for orthopedics and spinal surgery, for connecting motor handpieces when working with shaver and high-speed applications, and for connecting the Power Drill M1. Includes power supply cable, CAN bus connection cable, and packaging. Power supply connection 50/60 Hz 100–240 V 2305001</p>
	<p>Wireless footswitch 2305100</p> <p>For this:</p> <p>Plug-in power supply for wireless footswitch FW8002M/08 Backup cable for wireless footswitch 2305300</p>

5.4 Cables



Power cord

Included in initial shipment of PulsioFlex 6882747.

Product description	REF	Getinge order #
Power Cord	40109X (X=country specific number)	Country specific order number available upon request*



Arterial Connection Cable

For connecting the temperature sensor of the PiCCO Catheter to the device. Included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Arterial Connection Cable	PC80150*	6882742*



Injectate Sensor Cable

For clamping to the Injectate Temperature Sensor Housing 6882773. Included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Injectate Sensor Cable	PC80109*	6882741*



Pressure Output Adapter

For transferring the pressure signal from the PiCCO Module to an external device. 2 pieces included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Pressure Output Adapter	PC85200*	6882745*



Pressure Connection Cable

For connecting the pressure transducer to the device. 2 pieces included in initial shipment of PiCCO Module 6882748.















Product description	REF	Getinge order #
Pressure Connection Cable	PMK-206*	6882743*

*Also suitable for PiCCO₂



HF Monopolar Connecting Cables






HF-Monopolar Anschlusskabel

Anschluss Instrument <i>Connector for instrument</i>	Anschluss Gerät <i>Connector for unit</i>	Länge <i>Length</i>	Typen <i>Types</i>
WOLF - Resektoskope WOLF resectoscopes 	 ERBE (ACC / ICC) / BOWA (EU)	3 m	815.032
		5 m	815.052
	 ERBE (T-Serie) ERBE (T series)	3 m	815.132
		5 m	815.152
	 Martin (m-Version) / Berchtold / Aesculap	3 m	815.031
		5 m	815.051
<hr/> HF-Elektroden, monopolar Monopolar HF electrodes 	 Bovie / Valleylab / Erbe (Int.) / BOWA (Int.)	3 m	815.033
		5 m	815.053
	 BOWA (Int. / EU) Eschmann und andere Geräte mit 4 mm Stecker <i>Eschmann and other devices with 4 mm connectors</i>	3 m	815.034
		5 m	815.054
WOLF - Instrumente WOLF instruments 	 ERBE (ACC / ICC) / BOWA (EU)	3 m	8106.032
		5 m	8106.052
	 ERBE (T-Serie) ERBE (T series)	3 m	8106.132
		5 m	8106.152
	 Martin (m-Version) / Berchtold / Aesculap	3 m	8106.031
		5 m	8106.051
<hr/> HF-Elektroden, monopolar Monopolar HF electrodes 	 Bovie / Valleylab / Erbe (Int.) / BOWA (Int.)	3 m	8106.033
		5 m	8106.053
	 BOWA (Int. / EU) Eschmann und andere Geräte mit 4 mm Stecker <i>Eschmann and other devices with 4 mm connectors</i>	3 m	8106.034
		5 m	8106.054



Overview of the range

Lot: 31

Light Cables in new design



Fiber Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 <p>Set bestehend aus: Fiber Lichtleiter, Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509)</p> <p>* Die Lichtleiter können auch ohne Adapter bestellt werden. Adapter zum Anschluss an Fremdprodukte bieten wir separat an (siehe unten).</p>		1,6 mm	1,8 m	806616181	80661618*
			2,3 m	806616231	80661623*
			3,0 m	806616301	80661630*
		2,5 mm	1,8 m	806625181	80662518*
			2,3 m	806625231	80662523*
			3,0 m	806625301	80662530*
		3,5 mm	1,8 m	806635181	80663518*
			2,3 m	806635231	80663523*
			3,0 m	806635301	80663530*
		5,0 mm	3,5 m	806635351	80663535*
			2,3 m	806650231	80665023*
			3,0 m	806650301	80665030*
			3,5 m	806650351	80665035*

Fused *fusion* light cables, resistant to high temperatures

fusion Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 <p>Set comprises: Fiber Light Cable, adapter projector-light source-end (8095.07) and adapter endoscope-end (809509)</p> <p>*The <i>fusion</i> light cables can also be ordered without adapters and they are compatible with the same adapters.</p>		5,0 mm	2,3 m	806550231	80655023*
			3,0 m	806550301	80655030*
			3,5 m	806550351	80655035*

Adapters for light cables

for connection to **light sources** from the following manufacturers:

Wolf, Stryker..... 8095.07	
Storz	no adapter necessary
Olympus..... 8096.811	



for connection to **endoscopes** from the following manufacturers:

	Wolf..... 809509
	Storz, Stryker, Olympus..... 807001
	ACMI, Circon, Henke-Sass-Wolf..... 807002

