9

Sub





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: Valid until: 2020-03-11

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	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	lla 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





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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09**

Gay C Stade

Expiry Date: **2024-05-26**

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Page 1 of 4





Supplementary Information to CE 540595

Issued To: Teleflex Medical

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Number	Device Name	Intended purpose per IFU
Class III		
	EpiStar CSE - Spinal-Epidural Anaesthesia Kits	See CE 544836
	Spinostar Spinal Needles	See CE 560441
Class IIb		
10735	Sterile Percutaneous Nephrostomy Catheter	Puncture and dilation of percutaneous approaches into the upper urinary tract.
35404	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients through an existing tracheostoma.
14099	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients, in whom the stoma was created by percutaneous dilative tracheostomy.
58005	Sterile Ureter Stent	Routine drainage of the renal pelvis via the ureter or a ureter-skin stoma to an external collection site.
34924	Sterile Suprapubic Cystotomy Set	Routine suprapubic drainage of the bladder
31074	Sterile Ureterocutaneostomy Catheter	Routine drainage of urine through a ureterocutaneous stoma site.

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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Page 2 of 4





Supplementary Information to CE 540595

Issued To:

Teleflex Medical IDA Business and Technology Park Dublin Road

Athlone Co. Westmeath Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Transurethral Catheter	
MD 0101	Sterile Tracheostomy Retainer Set	
MD 0106	Sterile Rectal Tube	
MD 0101 MD 1102	Sterile Breathing Circuit	
MD 0101 MD 1102	Non-sterile Breathing Circuit	88/ 8998
MD 0101	Sterile Cricothyrotomy Set	3/ /4/3/3/3/3/3/3/3/3/3/3/3/3/3/3/3/3/3
MD 0102	Sterile Epidural Set	
MD 0101	Sterile EZ Blocker Kit	
MD 0106	Sterile Guidewire	
MD 0106	Sterile Kidney Stone Extractor	7 - 4/1
MD 0101	Sterile Tracheal Tube	
MD 0101	Non-sterile Tracheal Tube	CALEBRE
MD 0101	Sterile Laryngeal Mask	
MD 0101	Non-sterile Laryngeal Mask	

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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Page 3 of 4





Supplementary Information to CE 540595

Issued To: Teleflex Medical

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Laparoscopy Bag	
MD 0101	Sterile Bronchial Tube	
MD 0101	Sterile Suprapubic Cystotomy Set	
MD 0303	Sterile Drainage Tube	5
MD 0101	Sterile Tracheostomy Tube, Inner cannula	30)
MD 0106	Sterile Ureter Catheter	
MD 0102	Sterile Needle Introducer	
MD 0101	Sterile Percutaneous Nephrostomy Catheter	
MD 0106	Non-sterile Temperature Sensor	2 2 3 33.5
MD 0101	Sterile Breathing Bag	
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	ESSE

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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Page 4 of 4

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.





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: 2020-06-09

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone Co. Westmeath

Ireland

Service(s) supplied **Subcontractor:**

Arrow International CR, a.s. Design

Jamska 2359/47 **Manufacture** Zdar Nad Sazavou 59101

Arrow International CR, a.s. Design Prazska 209 Hradec Kralove 50004

Arrow Medical Ltd **Manufacture** Hatton Garden Industrial Estate

Kington Hereford HR5 3RB United Kingdom

Czech Republic

Czech Republic





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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor: Service(s) supplied

BBF Sterilisationsservice GmbH Radiation (Gamma Sterilization)
Willy-Rüsch-Straße 10/1

71394 Kernen Germany

Chelle Medical Limited Manufacture

Le Rocher P.O Box 221 Victoria Mahe Seychelles

Chemiczna Spóldzielnia Pracy Technochemia ETO Sterilization

ul. Fabryczna 3 05-600 Grójec Poland

Contract Medical International, spol. sr.o. Manufacture

Vážní 848 500 03 Hradec Králové Czech Republic





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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor:

Service(s) supplied

Daqing Medical Device (Tianjin) Co., Ltd 10A & 11A Tianzhi Industrial Center No.12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin People's Republic of China Manufacture

Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel

Manufacture

Forefront (Xiamen) Medical Devices Co., Ltd No. 28 Haijing East Road & No. 61 Haijing South Road Xiamen Area of China (Fujian) Pilot Free Trade Zone 361026 Xiamen, Fujian People's Republic of China Manufacture





Manufacture

ETO Sterilization

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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor: Service(s) supplied

Forefront Medical Technology (Pte) Ltd 35 Joo Koon Circle Singapore 629110

Singapore

M.E.M., Inc. Manufacture

8 Bishop Lane Madison Connecticut 06443

Medicoplast International GmbH

Heusweilerstrasse 100 DE-66557 llingen

Germany

USA

Parker Hannifin CSS Merrillville Manufacture

1201 East 86th Place

Merrillville IN, 46410 United States





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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor:

Service(s) supplied

Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas,

Ipoh Perak 30020

Malaysia

Manufacture

Professional Contract Sterilization Inc.

40 Myles Standish Blvd

Taunton

Massachusetts

02780-1026

USA

ETO Sterilization

safemed medical devices s.r.o

Trabantská 292 19015 Praha 9

Czech Republic

Manufacture





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: 2020-06-09

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor: Service(s) supplied

sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach

Germany

ETO Sterilization

ETO Sterilization Manufacture

SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang. Selangor Malaysia

SP Medical A/S Møllevej 1 4653 Karise Denmark

Design **Manufacture**

SP Medical Sp. z o.o. UI. Ceramiczna 2K 98-220 Zduńska Wola

Poland

Manufacture





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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor: Service(s) supplied

STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80

Velka Bites 59501 Czech Republic

Synergy Sterilisation (M) Sdn Bhd. **ETO Sterilization**

Plot 203

Kuala Ketil Industrial Estate

Kuala Ketil Kuala Ketil Kedah 09300 Malaysia

Synergy Sterilisation Kulim (M) Sdn. Bhd ETO Sterilization

Lot 71, Kulim Industrial Estate

Kulim Kedah 09000

Malaysia

ETO Sterilization





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: **2020-06-09**

Issued To: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Subcontractor:

Teleflex Medical Asia Pte. Ltd.

21 Merchant Road

#04-01

Royal Merukh S.E.A

058267 Singapore Service(s) supplied

Design Manufacture

Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4

34600 Kamunting Perak

Malaysia

Design

ETO Sterilization Manufacture

The Laryngeal Mask Company

(Malaysia) Sdn. Bhd. Lot 19 & 1920

Industrial Zone Phase 1

Kulim Hi-Tech Park

Kulim 09000

Malaysia

Manufacture





Certificate No:

CE 540595

Date:

2020-06-09

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 Rüsch, 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 4

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.





Certificate No:

CE 540595

Date:

2020-06-09

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.
05 August 2016	8571081	Addition of Contract Medical International, spol. sr.o. to the list of significant subcontractors. Addition of EZ Blocker non-active respiratory device.
09 January 2017	8665617	Change to the address of subcontractor (Forefront).
16 July 2018	8939923	Addition of Daqing Medical Device (Tianjin) Co., Ltd to the list of significant subcontractors.

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Page 2 of 4





Certificate No: **CE 540595**Date: **2020-06-09**

Issued To: Teleflex Medical

IDA Business and Technology Park

Dublin Road Athlone Co. Westmeath

Ireland

Date	Reference Number	Action
4 March 2019	7779566	Traceable to NB 0086.
Current	3124666	Certificate renewal. Addition of supplementary product information table.
		Removal of Control of Sterilization from Service(s) supplied for Arrow International CR, a.s. (Zdar), Arrow International CR, a.s. (Hradec Kralove), Contract Medical International spol. sr.o., SP Medical A/S, sfm medical devices GmbH, Teleflex Medical Asia Pte. Ltd. and Teleflex Medical Sdn. Bhd.
		Removal of Crucial Supplier from Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd. and The Laryngeal Mask Company (Malaysia) Sdn. Bhd.
		Addition of Manufacture to Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, M.E.M., Inc., Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd., and The Laryngeal Mask Company (Malaysia) Sdn. Bhd.
		Removal of Manufacture from Service(s) supplied for Arrow International CR, a.s. (Hradec Kralove)
		Addition of Degania Silicone Limited, safemed medical devices s.r.o and SP Medical Sp. z.o.o. as subcontractors for Manufacture.

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Page 3 of 4

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.





Certificate No:

CE 540595

Date:

2020-06-09

Issued To:

Teleflex Medical

IDA Business and Technology Park

Dublin Road Athlone

Co. Westmeath

Ireland

Date	Reference Number	Action
		Addition of STERIS AST CZ s.r.o., Synergy Sterilisation (M) Sdn Bhd., Synergy Sterilisation Kulim (M) Sdn Bhd., Chemiczna Spóldzieknia, Medicoplast International GmbH, Professional Contract Sterilization Inc., SINA-SterilGamma Sdn Bhd and Teleflex Medical Sdn. Bhd. as subcontractors for ETO Sterilization.
		Addition of BBF Sterilisationsservice GmbH as subcontractor for Gamma Sterilization.
		Removal of CeMed GmbH, Tianjin Medis Medical and Willy Rüsch GmbH
		Administrative correction of details for Arrow Medical Ltd, Chelle Medical Limited, Contract Medical International spol. sr.o., Daqing Medical Device (Tianjin) Co., Ltd, Forefront (Xiamen) Medical Devices Co., Ltd and SP Medical A/S.
		Change of address for Teleflex Medical Asia Pte. Ltd.
		Name change from Süddeutsche Feinmechanik GmbH (SFM) to sfm medical devices GmbH
		Name change from Parker Medical Systems Division -
		Merrillville to Parker Hannifin CSS Merrillville

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Page 4 of 4

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.





Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Teleflex Medical**

IDA Business and Technology Park

Dublin Road Athlone Co. Westmeath

Ireland

Holds Certificate Number: FM 544574

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

> The design and manufacture of non-active digestive tract devices; non-active gynaecological devices, non-active regional anaesthesia devices, non-active respiratory devices, non-active surgical devices, non-active urology devices and active surgical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-03-09 Effective Date: 2023-02-12 Latest Revision Date: 2023-01-26 Expiry Date: 2026-02-11

Page: 1 of 1

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

3.5 PiCCO Kits

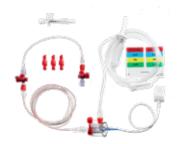
PiCCO Kits consists of:

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

RÜSCH ENDOTRACHEAL TUBES

The optimum tube for all applications. At RÜSCH, this demand is met thanks to an extraordinarily extensive and versatile range of tubes. All RÜSCH tubes feature an outstanding I.D. to O.D. ratio. Our high quality standards are reflected in the high-grade materials we use, which are tested according to the highest medical standards.

To meet the special requirements of paediatric patients, Teleflex's RÜSCH brand supplies a large variety of tracheal tubes in smaller sizes. Tracheal tubes for paediatric care are marked with black tip to ensure safe tracheal positioning.

CHILD AGE	TUBE I.D.	BLACK TIP LENGTH
1.	2.0-3.5 mm	20 mm
25.	4.0-5.0 mm	30/40 mm
614.	5.5-6.5 mm	40 mm

TRACHEAL TUBES:

- 1. Before using tracheal tubes with the connector pushed on halfway, it must be ensured that the connector is pushed into the tube shaft as far as it will go.
- 2. To improve the tight hold, it is advisable to clean with ethanol, both the contact surface of a connector that has been loosened once or removed and the corresponding tube shaft, before
- 3. This particularly applies to those cases in which the connector was completely removed first (e.g. for fibreoptic insertions), or was pushed on again after the tube had been shortened.

SUPER SAFETYCLEAR



PVC, WITH LOW-PRESSURE CUFF nasal/oral

sizes: I.D. 2.5-10.0 mm

semi-seated connector, valve for Luer and Luer-lock syringes, cupped atraumatic tip, continuous X-ray marker, black position indicator for correct tube placement, blue pilot balloon, graduated

CLEAR TRACHEAL TUBE MADE OF

- latex-free
- sterile



SUPER SAFETY	YCLEAR			Rü	SCH
REF.	ORDER SIZE/I.D.	0.D.	CUFFØ	LENGTH*	QTY
112480, Magill	2.5 mm	4.0 mm	8.0 mm	160 mm	10
	3.0 mm	5.0 mm	8.0 mm	170 mm	
	3.5 mm	5.3 mm	8.0 mm	190 mm	
-	4.0 mm	6.0 mm	10.5 mm	220 mm	
	4.5 mm	6.3 mm	10.5 mm	230 mm	
112482,	5.0 mm	6.7 mm	13.0 mm	250 mm	
Murphy, 1 eye	5.5 mm	7.3 mm	16.5 mm	280 mm	
X	6.0 mm	8.0 mm	18.5 mm	290 mm	
1	6.5 mm	8.7 mm	20.5 mm	300 mm	
000	7.0 mm	9.3 mm	24.0 mm	320 mm	
	7.5 mm	10.0 mm	26.0 mm	330 mm	
	8.0 mm	10.7 mm	26.0 mm	340 mm	
	8.5 mm	11.3 mm	28.0 mm	345 mm	
	9.0 mm	12.0 mm	28.0 mm	350 mm	
	9.5 mm	12.7 mm	29.0 mm	350 mm	
	10.0 mm	13.3 mm	29.0 mm	350 mm	

^{*} Length without connector

SAFETYCLEAR

CLEAR TRACHEAL TUBE MADE OF PVC WITHOUT CUFF

nasal/oral

sizes: I.D. 2.0-10.0 mm

semi-seated connector, cupped atraumatic tip, continuous X-ray marker, graduated

- latex-free
- sterile





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SAFETYCLEAR RUSC					CH
REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	LENGTH BLACK TIP	QTY
100380, Magill sizes: I.D. 2.0–10.0 mm	2.0 mm	3.0 mm	150 mm	20 mm	10
	2.5 mm	3.3 mm	160 mm	20 mm	
	3.0 mm	4.0 mm	170 mm	20 mm	
	3.5 mm	4.7 mm	190 mm	20 mm	
	4.0 mm	5.3 mm	210 mm	30 mm	
	4.5 mm	6.0 mm	230 mm	30 mm	
100382, Murphy, 1 eye sizes: I.D. 2.0-7.0 mm	5.0 mm	6.7 mm	250 mm	40 mm	
	5.5 mm	7.3 mm	280 mm	40 mm	
	6.0 mm	8.0 mm	290 mm	40 mm	
	6.5 mm	8.7 mm	300 mm	40 mm	
	7.0 mm	9.3 mm	320 mm	-	
	7.5 mm	10.0 mm	330 mm	-	
	8.0 mm	10.7 mm	340 mm	-	
	8.5 mm	11.3 mm	345 mm	-	
	9.0 mm	12.0 mm	350 mm	-	
	9.5 mm	12.7 mm	350 mm	-	
	10.0 mm	13.3 mm	350 mm	-	

 $^{{\}it * Length \ without \ connector}$



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICAL

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratii de conformitate CE
I.3. Certificatul CE	Certificat CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul
	picco					pulsion
DM000182799	Set de catetere pentru monitorul PiCCO2		PV2015L20-A		Germania	PULSION MEDICAL SYSTEMS SE
DM000182800	Set de catetere pentru monitorul PiCCO2		PV2014L22-A		Germania	PULSION MEDICAL SYSTEMS SE
DM000182802	Set de catetere pentru monitorul PiCCO2		PV2014L08-A		Germania	PULSION MEDICAL SYSTEMS SE
DM000182803	Set de catetere pentru monitorul PiCCO2		PV2014L16-A		Germania	PULSION MEDICAL SYSTEMS SE
DM000182804	Set de catetere pentru monitorul PiCCO2		PV2014L50-A		Germania	PULSION MEDICAL SYSTEMS SE
DM000182798	Senzor de injectare pentru monitorul		PV4046		Germania	PULSION MEDICAL SYSTEMS SE

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