Annex to the EC Certificate No. 50076-16-08

Valid from 2019-06-26 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-26

Devices/device categories included in the certificate:

Class II a:

Urology Device

- Foley /Heamaturia Catheter (Latex)
  - 2 Way Foley Catheter
  - 3 Way Foley Catheter
  - Preconnected Urological System
- Foley Catheter (PVC)
  - 2 Way Foley Catheter (Simplastic)
  - 3 Way Foley Catheter (Simplastic)
- Hyperthermia Bladder Silicone Catheter
- Urodynamic Catheter
- Suprapubic Catheter (PVC)

Respiratory Device

- Breathing Circuit
  - Catheter Mount
  - Heat & Moisture Exchanger (HME)
  - HME with Catheter Mount
  - Bacterial/Viral Filter
  - Bacterial/ Viral Filter with Catheter Mount
  - HME Filter
  - HME Filter with Catheter Mount
  - Rebreathing Bag
  - Multimask
- Endotracheal Tube with / without stylet
- Nasal Cannula
  - Nasal Cannula Set
  - Comfort Flo Plus Cannula

Gastrointestinal Device

- Rectal Tube

Gynecological Device

- Drainage Catheter
  - Word Catheter

Surgical Device

- Surgical Drainage Catheters
  - Pezzer
  - Malecot
- Laparoscopy Filter

Digitally signed by Ghereg Victor
Date: 2024.09.23 11:39:51 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Annex to the EC Certificate No. 50076-16-08

Valid from 2019-06-26 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-26

Devices/device categories included in the certificate:

Class II b:

Urology Device

- Foley Catheter Silicone
  - 2 Way Foley Catheter
  - 3 Way Foley Catheter
  - Preconnected Urological System
  - Brillant & Silflate Catheters
- Foley Catheter Latex (Hydrogel Coated)
  - 2 Way Foley Catheter (Sympacath/ Aquaflate Sympacath)
  - 3 Way Foley Catheter (Sympacath)
- Nephrostomy Catheter with/ without Stylet
- Suprapubic Catheter (Silicone)
- 2 Way Silicone Temperature Sensor Catheter

Respiratory Device

- Tracheostomy Tube
  - Crystal Clear Tracheostomy Tube

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-06-26
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50076-17-07

Valid from 2019-06-26 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-26

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.

Respiratory Device

- Nasopharyngeal Airways
- ET Stylet

Urology Device

- Intermittent Catheters (PVC) with/without Saline Water Sachet
- Intermittent Catheter (Latex)
  - Nelaton Type Catheters
  - Prefilled Syringe

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-06-26
Notified Body ID-number: 0124

ARTICLE 120 SELF-DECLARATION

EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM

FOR EXTENDED TRANSITION TO MDR

Legal Manufacturer (LM)	Name: Teleflex Medical Inc. Address: 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA
Authorized Representative	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland
Incoming Notified Body (MDR NB)	Name: BSI Netherlands Identification Number: CE 2797
Notified Body That Issued the Certificate Under MDD (MDD NB)	Name: SGS Belgium NV Identification Number: CE 1639

Teleflex Medical Inc. declares that the product(s) listed in Appendix A meet the provisions of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices.

This declaration is made on the basis that the product(s) listed in Appendix A are currently compliant to:

☒ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), and are intended to or have been confirmed to meet the provisions of Regulation (EU) 2017/745 (MDR)

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), Article 120(2) points (a) or (b) of MDR and are intended to meet the provisions of Regulation (EU) 2017/745 (MDR).

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), and Article 120(3c) of MDR

Furthermore, Teleflex Medical Inc. declares:

☒ A formal application has been lodged in accordance with Section 4.3, first subparagraph, of Annex VII MDR before MDD certificate expiration or before 26 May 2024. The LM and MDR NB have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

☒ A Quality Management System (QMS) will be implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR) prior to 26 May 2024. Documentation regarding this QMS has been included as part of the application for conformity assessment made to the MDR NB. The MDR NB will complete an assessment of the QMS as part of its conformity assessment activities.

☒ Post-market surveillance, market surveillance, vigilance, and economic operator requirements will be conducted pursuant to Article 120(3e) of the Regulation (EU) 2017/745 (MDR).

☒ The extended transitional period for the product(s) listed in Appendix A shall end on the dates stated in Appendix A, as set forth in Article 120 (3) of the MDR.

Approvals

Name and Title of Approver:	Kim Campbell, Sr. Regulatory Affairs Manager
Signature of Approver:	
Date Approved:	11-Jul-2023
Place of Issue:	Teleflex Medical Inc. 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA

Change History for Declaration of Conformity Addendum:

Revision	Date	Change Order Number or N/A	Reason for Revision
00	See Agile	DCO-068469	Initial Release through DCO-068469

APPENDIX A

Product Name	Product Code(s)	MDD EC Certificate(s) No	MDD EC Certificate(s)Expiry Date	End date for Transition Period	MDR Product Class	MDR Class Rule	MDR Conformity Assessment Route(s)	Scheduled MDR Submission Date
Metal Manual Ligation System (Metal Ligating Clips)	001200 001204 001201 001205 002200 002204 003200 003204 004200 004204 005200 523100 523135 523160 523170 523300 523335 523360 523370 523700 523735 523760 523770 523800 523835 523860 523870 533700 533702 533735 533737 533800 533802 533835 533837 533860 533862 533870	BS EN ISO 13485:2016 – US97/10878 European Directive (Design Examination) 93/42/EEC – US19/819943634	14-JUL-2023	31-DEC-2028	Class III	Rule 8	Annex IX	30-Aug-2021

	533872 534735 534737 534835 534837							

ARTICLE 120 SELF-DECLARATION

EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM

FOR EXTENDED TRANSITION TO MDR

Legal Manufacturer (LM)	Name: Teleflex Medical Inc. Address: 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA
Authorized Representative	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland
Incoming Notified Body (MDR NB)	Name: BSI Netherlands Identification Number: CE 2797
Notified Body That Issued the Certificate Under MDD (MDD NB)	Name: SGS Belgium NV Identification Number: CE 1639

Teleflex Medical Inc. declares that the product(s) listed in Appendix A meet the provisions of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices.

This declaration is made on the basis that the product(s) listed in Appendix A are currently compliant to:

☒ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), and are intended to or have been confirmed to meet the provisions of Regulation (EU) 2017/745 (MDR)

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), Article 120(2) points (a) or (b) of MDR and are intended to meet the provisions of Regulation (EU) 2017/745 (MDR).

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), and Article 120(3c) of MDR

Furthermore, Teleflex Medical Inc. declares:

☒ A formal application has been lodged in accordance with Section 4.3, first subparagraph, of Annex VII MDR before MDD certificate expiration or before 26 May 2024. The LM and MDR NB have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

☒ A Quality Management System (QMS) will be implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR) prior to 26 May 2024. Documentation regarding this QMS has been included as part of the application for conformity assessment made to the MDR NB. The MDR NB will complete an assessment of the QMS as part of its conformity assessment activities.

☒ Post-market surveillance, market surveillance, vigilance, and economic operator requirements will be conducted pursuant to Article 120(3e) of the Regulation (EU) 2017/745 (MDR).

☒ The extended transitional period for the product(s) listed in Appendix A shall end on the dates stated in Appendix A, as set forth in Article 120 (3) of the MDR.

Approvals

Name and Title of Approver:	Kim Campbell, Sr. Regulatory Affairs Manager
Signature of Approver:	
Date Approved:	11-Jul-2023
Place of Issue:	Teleflex Medical Inc. 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA

Change History for Declaration of Conformity Addendum:

Revision	Date	Change Order Number or N/A	Reason for Revision
00	See Agile	DCO-068469	Initial Release through DCO-068469

APPENDIX A

Product Name	Product Code(s)	MDD EC Certificate(s) No	MDD EC Certificate(s) Expiry Date	End date for Transition Period	MDR Product Class	MDR Class Rule	MDR Conformity Assessment Route(s)	Scheduled MDR Submission Date
Polymer Manual Ligation System (Polymer Ligating Clips)	544220 544230 544233 544240 544243 544250 544253	93/42/EEC – US19/819943647 EC Design Examination Certificate –US19 US19/819943636	14-JUL-2023	31-DEC-2028	Class III	Rule 8	Annex IX	15-Dec-2022

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 2797):

Gary E Slack, Senior Vice President Medical Devices

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

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EC Certificate - Full Quality Assurance System

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**

EC Certificate - Full Quality Assurance System

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	
MD 0101	Sterile Cricothyrotomy Set	---
MD 0102	Sterile Epidural Set	---
MD 0101	Sterile EZ Blocker Kit	---
MD 0106	Sterile Guidewire	---
MD 0106	Sterile Kidney Stone Extractor	---
MD 0101	Sterile Tracheal Tube	---
MD 0101	Non-sterile Tracheal Tube	---
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**

EC Certificate - Full Quality Assurance System

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	---
MD 0101	Sterile Tracheostomy Tube, Inner cannula	---
MD 0106	Sterile Ureter Catheter	---
MD 0102	Sterile Needle Introducer	---
MD 0101	Sterile Percutaneous Nephrostomy Catheter	---
MD 0106	Non-sterile Temperature Sensor	---
MD 0101	Sterile Breathing Bag	---
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	---

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

By Royal Charter

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:	**2020-06-09**
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 Zdar Nad Sazavou 59101 Czech Republic	**Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	**Design**
Arrow Medical Ltd Hatton Garden Industrial Estate Kington Hereford HR5 3RB United Kingdom	**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:	**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 Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**
Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe Seychelles	**Manufacture**
Chemiczna Spółdzielnia Pracy Technochemia ul. Fabryczna 3 05-600 Grójec Poland	**ETO Sterilization**
Contract Medical International, spol. sr.o. Vážní 848 500 03 Hradec Králové Czech Republic	**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:	**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**

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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:	**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	**Manufacture**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Manufacture**
Medicoplast International GmbH Heusweilerstrasse 100 DE-66557 Illingen Germany	**ETO Sterilization**
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville IN, 46410 United States	**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:	**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**

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

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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:	**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	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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By Royal Charter

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:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Teleflex Medical Asia Pte. Ltd. 21 Merchant Road #04-01 Royal Merukh S.E.A 058267 Singapore	**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**

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EC Certificate - Full Quality Assurance System Certificate History

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.

EC Certificate - Full Quality Assurance System Certificate History

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.

EC Certificate - Full Quality Assurance System Certificate History

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.

EC Certificate - Full Quality Assurance System Certificate History

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 Spółdzieknia, 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

By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 540596**

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

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.
Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.
The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.

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):

Gary E Slack, Senior Vice President Medical Devices

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

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

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 0102	Sterile Intraosseous Vascular Access System	--
MD 1104	Non-sterile Intraosseous Vascular Access System	
MD 0102	Sterile Powered Bone Access	--
MD 1104	Non-sterile Powered Bone Access	
MD 0102	Sterile Sternal Intraosseous Device	--
MD 0101	Sterile Silicone Foley Catheter	--

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

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0301	Intraosseous Vascular Access System Stabilizer	--
MD 0102	Powered bone access connector	--
MD 0101	Tracheostomy Tube Accessories	--
MD 0102	Tuohy Borst Adaptor	--
MD 0102	Syringe	--
MD 0101	Urology Dilator	--
MD 0101	Guedel Airway	--
MD 0101	Intrauterine Catheter Set	--
MD 0101	Sterile Container	--
MD 0101	Neckband	--
Sterility aspects only		
---	Procedure Packs under article 12	---

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

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
ArcRoyal Virginia Road Kells, Co. Meath Ireland	**Manufacture**
Arriol International Corporation Carretera San Isidro KM 17 Zona Franca San Isidro Santo Domingo Este Dominican Republic	**ETO Sterilization** **Manufacture**
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	**Manufacture**
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
CeMed GmbH Im Oberdorf 41 72419 Neufra Germany	**Assembly** **Packaging**
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	**Radiation (Gamma Sterilization)**
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	**Manufacture**
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton MN 55112 USA	**Manufacture**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist 42944 Taichung City Taiwan	**Manufacture**
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	**Radiation (E Beam Sterilization)**
Medical Service GmbH Luisenstraße 8 75378 Bad Liebenzell/Unterhaugstett Germany	**Assembly** **Packaging**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Mediplast Israel Ltd. 7 Hayarkon St. P.O. Box 13214 Industrial Zone Yavne 8122710 Israel	**ETO Sterilization**
Rose GmbH für Medizintechnik Gottbillstraße 25-30 54294 Trier Germany	**ETO Sterilization**
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	**ETO Sterilization** **Manufacture**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Sparton Onyx, LLC 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	**Manufacture**
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Steritec, Inc. P.O. Box 1969 1705 Enterprise Street Athens, TX 75751 United States of America	**ETO Sterilization**
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**

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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 540596**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**ETO Sterilization** **Manufacture**
Viant San Antonio, Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 United States of America	**Manufacture**
Viant Upland, Inc. a.t.a. (formerly) Lake Region Medical 2052 West 11th Street Upland CA 91786 USA	**Manufacture**
Willy Rüsch GmbH Willy-Rüsch-Straße 4-10 71394 Kernen i.R., Germany	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

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	7325720	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture.
25 August 2009	7399908 7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope.
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities.
23 May 2012	7778468	Correction of significant subcontractor address.
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC.
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.
10 February 2016	8455693	Removal of Vidacare LLC from list of significant subcontractors. Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture. Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture. Removal of repeated use of word 'devices' from scope.
28 July 2017	8762518	Change of address for Coastal Life Technologies. Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors.
04 March 2019	7779566	Traceable to NB 0086.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
Current	3124053	Certificate renewal. Addition of supplementary product information table. Update to scope to include non-active sterile urology catheters. Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüsch GmbH. Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd. Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüsch GmbH. Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C. Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

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

Date	Reference Number	Action
	3124053	Addition of Degania Silicone Limited for Manufacture Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Mediplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization Addition of Iotron Industries USA for E-beam Sterilization Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization.

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

Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

Certified location:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

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. 50076-Z7-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-06-26 to 2024-05-26

Registration No.: 50076-16-08

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
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

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

Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

Certified location:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

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. 50076-Z7-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-06-26 to 2024-05-26

Registration No.: 50076-17-07

DEKRA Certification GmbH • Handwerkstraße 15 • D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
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

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Teleflex Medical Sdn. Bhd.

Scope of certification:

Design and development, and manufacture of (sterile and nonsterile) rectal tubes, tamponade catheters, External catheters, drainage catheters, breathing circuits, bronchial tubes, laryngoscope blades, naso-pharyngeal tubes/kits, tracheal tubes/sets, tracheostomy tubes/kits, surgical drainage catheters, nephrostomy catheters, suprapubic catheters/sets and transurethral catheters for the areas of urology, gastroenterology, gynecology, surgical and respiratory care. On-site ethylene oxide sterilization.

Certified location:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50076-R1-00.

Certificate registration no.:	50076-14-02	Certificate valid from:	2021-07-23
Validity of previous certificate:	2021-07-22	Certificate valid to:	2024-07-22

DEKRA Certification GmbH • Stuttgart • Handwerkstraße 15

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-07-23

bsi.

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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

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bsi.

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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

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DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Richard Wolf GmbH
Herr Wulf Brunow
Pforzheimer Str. 32
75438 Knittlingen
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Karin Heckel
Phone +49.711.7861-3427
Fax +49.711.7861-2615
Email karin.heckel@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2024-08-16

Subject: Notified Body Confirmation Letter

Our reference: 50593-CoL-02 Rev. 1

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Brunow,

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from the following manufacturer for the devices listed in the annex:

Richard Wolf GmbH
Pforzheimer Str. 32
75438 Knittlingen
Deutschland

SRN Number: DE-MF-000007048

Table 1 identifies the devices for which a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR has been concluded between Richard Wolf GmbH and DEKRA Certification GmbH and for which DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the DEKRA Certification GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 3 identifies the products or product groups and EC certificates according to MDD 93/42/EEC for which Richard Wolf GmbH intends to make use of the option for extension of the validity of the EC certificates. For these devices DEKRA Certification GmbH confirms that an agreement between Richard Wolf GmbH and DEKRA Certification GmbH is in place about the surveillance of the products according to Regulation (EU) 2017/745 Article 120 but a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR is still pending.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate. Additionally, should Richard Wolf GmbH intend to make use of the extension of the validity of the EC-certificates, involvement of a Notified Body for continued surveillance is required.

If Richard Wolf GmbH has intentions to make use of the option for extension of the validity of the EC certificates (see Table 1) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

the following conditions have to be met:

- Richard Wolf GmbH or its Authorized Representative has to ensure that a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the written agreement not to be signed acc. to the mentioned timelines, the EC certificates mentioned in the Table 1, cannot be considered valid after 26. September 2024.

This confirmation letters with the registration nos. 50593-CoL-00lr, Rev. 1 and 50008-CoL-01, rev.00 are invalid with immediate effect.

Validity of this confirmation letter:

For products included in table 1 and 2:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607

For products included in table 3:

Until the latest: 2024-09-25.

On behalf of the Notified Body,

Digitally signed by Stephanie Donner
Date: 2024-08-16 11:31:23+02:00

Stephanie Donner
2024-08-16

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50593-CoL-02 Rev. 1

Table 1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification	Agreement for Conformity Assessment ~~(if applicable)~~
4792.803 PUNCTURE NEEDLE SET 18G WL 150MM	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
4993692 RF INSTRUMENT BIPO Ø 2.5MM WL 350MM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
4840764 TITANIUM CLIP FOR TEM	Class IIb implantable non-WET device	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
412700 HAND BLOWER	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-17-04 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
8289.24 SUCTION TUBE BIPO Ø 3.2MM WL 240MM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A22081363
4712348 UNIVERSAL SEALING VALVE 1-6FR	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-17-04 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
4170502 INSUFFLATION TUBE SET L 3M	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
2235031	Class IIb excluding Class	N/A	Certificate: 50593-16-05	Offer/Order No.: A24011294

INSUFFLATOR 45 EVAC + HEAT FR 45L/MIN	IIb implantable non-WET		with Annex 0 dd. 2020-04-01; NB: 0124	
4170504 SMOKE EVACUATION FILTER	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
4170503 SMOKE ASPIRATION TUBE SET L 2.7M	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
2305001 MOTOR CONTROL UNIT 2305	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
41702208 TUBE FOR SUCTION	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A24011294
4171223 IRRIGATION TUBE SET SPIKE L 3M	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A22081363
2225001 IRRIGATION PUMP FOR HYS/URO/LAP	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A22041101
100506 PIEZOWAVE 2 CONTROL UNIT	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A22041101
2260001 HF SURGERY GENERATOR 400KHZ	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124	Offer/Order No.: A23011716

Table 2

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification	Agreement for Conformity Assessment ~~(if applicable)~~
8250.10 8267.10 8267.12 8267.14 8267.15 8267.21 8295.35 8243.461 8379.672 8295.50 8863.75 8863.80 8267.35 8383.551 8243.901 8384.66 8383.55 8383.66 8302.11 8303.10 8303.11 8302.101 8399.95 8436.201 8436.101 8399.901 8436.151 8436.251 8436.701 8436.301 8436.601	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8654.12 8654.67 8654.68 8654.16 8668.12 8654.17 8654.18 8653.18 865415 8673324 8906.181 8309.123 8309.121 8906.131 8906.151 8906.111 8913.11 8928,90 8934.175 8921.115 8923.115 8921.111 8923.113 8924.103 8924.125 8921.113 8924.123 8903.121 8903.103 8903.101 8903.123 8934.15 8921.105 8921.101 8921.123 8921.103 8921.125 8923.103 8923.125 8924.115 8923.123	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8924.113 8921.121 8962.19 8383.552 8435.903 8435.902 8435.953 8435.901 8435.952 8435.951 8435.968 8435.956 8435.966 8435.963 8632.126 8632128 8654.175 8659.175 8673226 8673026 8673224 8673024 8673022 8791.701 8792.591 8792.581 8968.675 8868.941 8869.921 8871.721 8871.586 8871.562 8874.121 8874.123 8874130 88741301 8874129 8923.921 8943.901 8934.951 892506003	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

15360022 15360023 15360021 892501625 892506625 892206318 8968.012 8968.015 8652.0447 8650.0347 8650.0447 8650.0147 8650.0247 8650.0547 8650.0647 8672.0147 8672.0247 8672.0347 8672.0447 8677.0147 8686.0347 8686.0247 8688.0147 8686.0147 86720257 86720457 86770157 892203120 892203220 88660091 88660092 8905.3315 8905.3513 8905.3515 8905.3313 8919.3311 8919.3312 8919.3512 8919.3313 8919.3511 8919.3513	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8929.2215 891203213 89121.0544 89121.0542 89121.0640 89121.0540 891221952 891222754 891221962 891222762 891222452 891222750 891222462 891234052 891237012 891532050 891532040 891532070 891532090 891641140 891643011 891646011 891242725 891641155 891644511 891242750 891242761 89150.3000 89160.3015 89160.3001 89150.3003 891511000 891510012 891634521 891633522 891631270 891632260 891638021 891636021 891636022 891631521	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

891633021 891534515 891631255 891632245 89160.1009 891800021 891202015 891800031 89250.1004 89250.1003 89250.2025 89250.2125 89120.2012 8868.921 8868.922 8868.923	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
83912257 83912207 83912107 83912087 83912197 83912097 83912187 83912267 83902207 83902187 83902197 83902257 83902267 83944907 83931897 83934945 83931877 83931887 83934887 83931907 83931917 83932917 83934907	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

83932925 83931867 83932935 83941897 83952257 83976547 83954897 83951877 83952448 83954907 83962047 83962267 83962367 83962347 83961877 83952347 83952048 83952268 83976558 83952148 83952368 83962257 892501925 892506925 83932297 83942427 83942537 83942307 83941937 83942507 83932427 83932537 83932237 83933457 83932497 83931937 83942297 83932507 83932307 83943457	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

83942237 83942497	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
83941877	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8391.501 8393.511 8393.502 8393.501 8393.503 8393.512 8394.512 8394.502 8394.503 8394.511 8645.6002 8962.6072 8962.6052 8962.6042 8642.6312 8962.6022	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8962.6102 8959.6802 8992.6402 8959.6212 8645.6502 8952.6212 8952.6002 8952.6112 8962.6002 8642.6002 8992.6302 8642.6502 8642.6812 8952.6502 8954.6802 8968.6802 891634530 8792.623	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8840.762 8866.951 823400003 823400002 823400001 891603000 89240.1624 89240.3904 89240.3903 89240.1904 89240.1052 89240.1903 89240.2325 892409020 892409035				
892206500 8403.00 8403.001 8370.00 8370.25 8371.10 8371.00 8517.00 8391505 8393508 8393519 8391506 8393507 8393518 8394507 8394518 8394508 8394519 8393509 8394509 8397.655 8395.489 8395.187 8395.214 8395.225 8395.236	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8395.204 8395.226 8395.244 8395.234 8395490 8396187 8396204 8396226 8396225 8396234 8396236 8397.654				
8389.991 8385.50 8941.951 8941.901 8383.78 8934.981 8415.11 8415.03 8415.12 8415.02 8415.13	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8923.931 8934.95 8393533 8390533 8394533 8391533 8391934 8390934 8396902 8397902 8395902 8632.726 8632728 8650.744 8650.734 8650.724 8650.714 8667.111	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8670.111 8673126 8673124 8673122 8968.111 8968.101 8792.504 8792.503 8792.764 8874150 8874.151 8874.152 8874.131 8874.153 8921.134 8924.134 8923.134 8921.132 8923.132				
8934.915 8945.915 8943.915 892206041 892206541 892206441 15570643 15570644 892606004 892606036 892206038 892206538 892206118 892206438 8964.121 8965.141 8966.151	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
89220.1027 89220.1147 89220.1047 89220.1068 89220.1167	Class I devices that qualify as re-usable surgical instruments		Certificate: 50593-16-05; NB: 0124	Offer/Order No.: A20061068

89220.1088 89220.1087 89220.3007 15208.255 89220.1007 89220.3008 15208.257 15208.258 89220.1017 89220.1038 89220.1137 89220.1037 89220.1157 89220.1057 89220.1078 89220.1098 15208.260 15208.261				
15208.262 15208.263 15208.264 15208.265 15208.266 89220.1018 89220.1117	Class I devices that qualify as re-usable surgical instruments		Certificate: 50593-16-05; NB: 0124	Offer/Order No.: A20061068
892209510 892209505 892209515 892209508 892209507 8693.0147 892209210 892209204 892209104 892601116 892601115 892601119 892601117 892209009 892209008 892209404	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

892209007 892209304 892209608 88660093 892209607 892209606 891014090 891013050 891013070 891013060 891015050 891014070 891015060 891013080				
891014080 891015070 891013510 891014100 891013714 891013612 891203203 891234073 891232070 891234077 891240200 891511709 891611103 891511708 891611102 891511710 891611101 891611110 891607001 891800020 891800030 891800900 891800700 891800800 89220.1508 89220.1507	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

892207007 892207017	Class I devices that qualify as re-usable surgical instruments		Certificate: 50593-16-05; NB: 0124	Offer/Order No.: A20061068
89260.1108 89260.1114 89260.1113 8379.732 8383.65 865319 891511011 891511055 891511075 891511010 891511065 891511095 891511085 891511008 891511009 891511006 891511105 891511007 891511005	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8734.686 8278.01 828.051 8734.606 7264.601 828.03 829.03 828.05 829.05 828.07 829.07 8953.60 8734.656 830.07 829.051 7264.611 828.10 829.10 7223.60	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

7223.65 8148.01 8280.26 8148.02 8280.22 8280.23				
829.603 828.605 829.601 828.651 8488.025 8488.063 8404.62 8281.33 8486.601 8488.951 8488.952 8488.953 8488.954 8486.611 8488.04 8488.02 8282.37 8486.621 8488.121 8283.52 8281.311 8283.51 8282.33 8404.81 8489.096 8283.53 8403.10 8280.47 8488.096 8280.42 8280.41 8280.43 8280.46 8489.063 8404.71	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8489.04 828.244 8462.62 8913.60 8462.64 8465.61				
8464.61 8465.63 8464.63 8466.651 8650.684 8650.664 8650.774 8650.654 8650.644 8650.614 8650.604 7265.611 7265.601 8242.651 8242.652 8242.611 8243.403 8243.711 8242.601 8243.404 8242.602 8243.603 8242.603 8243.604 8242.604 8243.701 8383.691 8383.311 8389.911 8391.504 8393.504 8393.514 8393.505 8393.506 8394.515	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8393.515 8394.505 8394.514 8394.506 8404.018 8404.017				
8488.041 8488.042 8486.602 8486.604 8486.614 8486.624 8672.604 8672.654 8736.685 8735.685 8756.201 8792.621 8792.632 8968.671 8968.601 8792.636 8792.671 8840.604 8840.605 8962.6078 8959.6808 8992.6408 8962.6058 8962.6048 8962.6028 8962.6108 8959.6218 8642.6318 8645.6508 8645.6008 8964.671 8964.601 8992.621 8993.235 8992.6308	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

8642.6508 8962.6008 8952.6508 8642.6008 8954.6808 8952.6008				
8952.6118 8642.6818 8952.6218 82530.0704 8968.6808 82530.0605 82530.0405 82530.0604 82530.0601 82530.0404 89240.1034 89240.1125 89230.1803 89230.1004 89230.1125 89240.1044 89230.1003 89240.1013 89240.1023 89240.1003 89240.1703 89240.1024 89240.1004 89240.1014 89240.2025 89240.2225 89240.2125 89240.3003 89240.3014 89240.3004 89240.3023 89240.3013 89240.3024 892406202 892406025	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

892406002				
8296.51 8667.98 8667.965 8693.93 8677.93 8667.93 8667.96 8688.94 8654998 8667.961 8667.966 8667.971 8667.981 8670.965 8670.961 8670.981 8677931 8677981 8677.961 8693.961 8923.135 891610070	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8383.611 8436.511 8436.521 8436.501 8385.301 8869.991 8869993 89160.3003 89160.3002 89160.3005	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068
8791.601 8791.691 891341055 89140.0605 89140.0405 89140.0505 89140.0102	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

89140.0103 89140.0202 89140.0122 89140.0101 89140.0205 89140.0502				
89140.0305 89140.0602 89140.0302 89140.0105 89140.0402 891432103 891432101 891432102 891432122 892409945 892409445	Class I devices that qualify as re-usable surgical instruments		N/A - Device did not require a Notified Body certificate under Directives	Offer/Order No.: A20061068

Table 3

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4844120	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-17-04 with Annex 0 dd. 2020-04-01; NB: 0124
4844255	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-17-04 with Annex 0 dd. 2020-04-01; NB: 0124
4565901M	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-17-04 with Annex 0 dd. 2020-04-01; NB: 0124
4170.2228	Class I devices placed on the market in sterile condition	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8703.524	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8703.534	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8702.514	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8703.514	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8702.524	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8702.534	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8704.524	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8708.534	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8708.517	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8708.518	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8701.534	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8701517	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8701518	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654.911	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654.981	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654.982	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654.985	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654.986	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8677.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8688.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8650.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8650.0245	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8650.0345	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8650.0445	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8650.0545	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8650.0645	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8652.0445	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8672.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8672.0245	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8672.0345	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8672.0445	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8686.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8686.0245	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8686.0345	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8693.0145	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8632.027	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8632.026	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86720255	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86720455	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8632029	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8632028	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654987	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654990	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654991	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654992	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654993	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654994	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654995	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654996	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8654997	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8302.08	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8302.12	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8302.15	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8677.224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8688.224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8970.011	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8659.071	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8680.204	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8680.205	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8680.224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8680.225	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8663.3741	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8655.374	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8655.3841	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8655.334	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8655.3441	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8653.021	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8653.018	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8653.224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86592351	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8970010	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86770155	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
49700103	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
49700113	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8674205	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8674224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8674234	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8681205	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8681224	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8675322	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8675324	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8675424	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8675426	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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2303.011	Class IIa	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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823.04	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

823.05	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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48423.095	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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4622.1313	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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4623.0243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
4653.023	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8653.02	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8653.131	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8653.132	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

4659.1613	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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4609.2513	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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4623.0223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
4622.1323	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
4610.0223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8609031	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8622131	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8622133	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8623022	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

862309	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
865303	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8659163	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
4624.1313	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8416011	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8416031	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8416091	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
46300223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
46300243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
46310243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86782201	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

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86782204	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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86782408	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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86782480	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

86782601	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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86792201	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86792202	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86792204	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
86792205	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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46782205	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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46530213	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

46530243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
46782202	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
46782203	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8416.09	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8422.131	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8422.151	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8422.351	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8423.09	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8423.19	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8424.131	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8424.151	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8426.141	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8688.93	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8688.95	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83930927	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83930937	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83931827	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931837	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83934837	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8390222	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8390223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8390226	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8391226	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83902227	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902237	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912077	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912217	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912227	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912237	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8390215	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8390224	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8390227	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8391215	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8391224	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8391227	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902157	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902247	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902277	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912157	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912247	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83912277	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394621	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394622	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394623	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394624	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83946217	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83946227	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83946237	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83946247	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8388201	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8388202	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8388203	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83882017	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83882027	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83882037	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8388200	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83882007	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393192	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393193	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393194	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393197	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393198	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393199	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393200	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393210	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393220	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393229	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393230	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393240	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393242	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393249	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393250	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393256	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393258	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394192	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394193	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394194	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8394197	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394198	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394199	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8394220	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394223	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8394230	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394240	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394242	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394249	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8394250	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394258	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931927	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931947	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931977	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931987	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83931997	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83932007	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83932407	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83932567	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83932587	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83941927	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83941947	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83941977	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83941987	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83941997	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83942007	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83942207	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83942407	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83942587	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393246	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393248	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394243	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394246	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394248	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83932437	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83932467	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83942467	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83942487	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.292	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.091	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.092	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.091	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.092	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8392.181	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.181	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.186	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.195	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.281	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393.285	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.289	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8393.483	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.485	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.486	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.487	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.488	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.181	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.195	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.281	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393.041	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.045	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.081	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.041	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.081	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.292	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.183	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.184	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.287	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.184	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.093	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393.182	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.185	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.187	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.282	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.283	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.288	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.293	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.482	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.494	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.187	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.293	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8393.044	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.188	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.189	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.291	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.490	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.189	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.490	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
4393.040	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383.426	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383.428	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8840.711	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

84420.0004	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
84420.0005	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
84420.0006	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8840.712	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8785.642	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8242.301	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8379.452	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8379.462	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8379.482	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383.40	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383.423	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8384.40	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8384.423	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930031	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930032	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930033	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930034	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930035	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839300312	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839300322	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839300332	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839300342	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

839300352	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930041	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839300412	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8391.715	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.705	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.714	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.704	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8394.714	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8391.742	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8393.741	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83930037	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

83930038	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839400310	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839400320	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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839400332	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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839400352	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
839400382	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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839400412	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8383.811	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383.812	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

8383.813	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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8291.102	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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84420.4007	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8840.731	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8383429	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

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5592606	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
5592614	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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2235021	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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2225023	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000.001	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000.002	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000.003	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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3000.011	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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80622	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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3000512	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000513	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000514	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000529	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000560	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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100681	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

100751	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
100691	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
2260002	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
2330001	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8424.141	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
3000501	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
89220.1028	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
15208.263	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
15208.264	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
15208.265	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
15208.266	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

89220.1018	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
89220.1117	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
892207007	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
892207017	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
89220.1137	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902107	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
83902097	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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83902087	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
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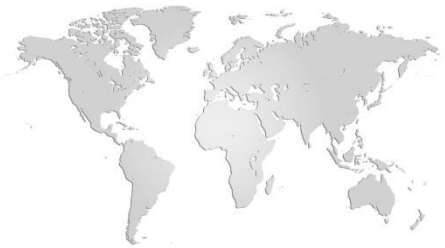
8394253	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
8397.654	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124
892209010	Class I device that qualify as re-usable surgical instrument	N/A	Certificate: 50593-16-05 with Annex 0 dd. 2020-04-01; NB: 0124

CERTIFICATE



EN ISO 13485:2016 + AC:2018 + A11:2021

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 Str. 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.:	50593-21-00_EN	Certificate valid from:	2024-01-30
Validity of previous certificate:	2024-01-29	Certificate valid to:	2024-11-28

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

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

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2024-01-30

Annex to the Certificate No. 50593-21-00

valid from 2024-01-30 to 2024-11-28

The following locations/companies belong to the certificate above:

	Headquarters	**Certified location**	**Scope of certification**
	Richard Wolf GmbH	Pforzheimer Str. 32 75438 Knittlingen Germany	see page 1
	at the following locations/at the companies at the following locations		**Scopes of certification**
1.	Richard Wolf GmbH	Reuchlinstr. 10-11 10553 Berlin Germany	Manufacture of flexible and rigid endoscopes

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2024-01-30

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

Lot: 253

RICHARD WOLF
spirit of excellence

Illustration

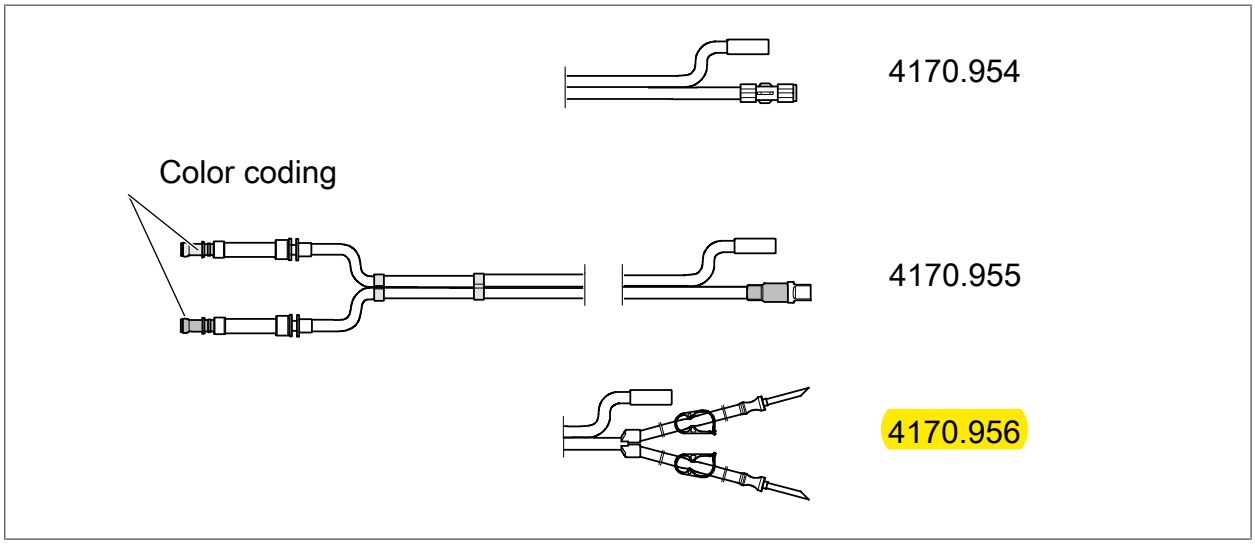


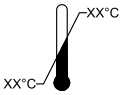
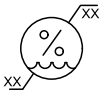
Fig. 1

Item number	Description
4170.954	**Irrigation tube**: With Luer-Lock, for connection to the irrigation tube of a suction and irrigation tube set, e.g., irrigation tube of the Endo-Irrigator 2211 **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters
4170.955	**Irrigation tube**: With SAFE-LOCK®, for connection to an irrigation container. **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters
4170.956	**Irrigation tube**: With 2 piercing spikes, for connection to an irrigation container. **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters

8.1 Labeling

Symbols	Designation
	Follow the manual
	Caution
REF	Product number
LOT	Lot code
	Manufacturer
	Manufacturing date
	Number, amount

RICHARD WOLF GmbH
Pforzheimer Straße 32
75438 Knittlingen

Symbols	Designation
	Expiry date
	Sterilized with ethylene oxide
	Single sterile barrier system with protective packaging inside (sterilized using ethylene oxide)
	Do not reuse!
	Do not resterilize
	Keep away from sunlight!
	Store in a dry place!
	Temperature, limitation
	Humidity, limitation
	Do not use if package is damaged
	Contains phthalates or phthalates are present: diethylhexylphthalate (DEHP)
	CE marking in accordance with Medical Devices Directive 93/42/EEC. **Applies only** if the **product and/or packaging bears this marking**. Products in Class IIa and higher and sterile products or products with a measuring function in Class I are also marked with the four-digit identification number of the notified body.

Operating, storage, transport, and shipping conditions

Disposable items, sterile products	Follow the instructions on the packaging!

ATTENTION

Store sterile products in their original packaging until use.
Improper storage can lead to loss of sterility.

ATTENTION

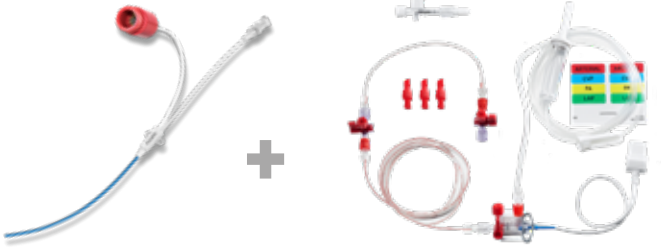
The relevant regulations and laws valid in the country of use must be observed when disposing of the product.
▷ For further information, please contact the manufacturer.

Lot: 312

3.5 PiCCO Kits

PiCCO Kits consists of:

PiCCO Catheter + **Monitoring Kit**



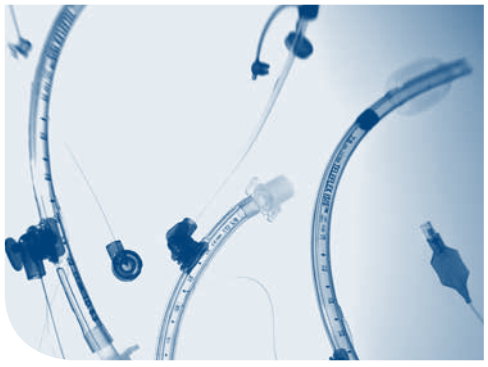
Additional information about the PiCCO Catheter see chapter 3.1; page 11

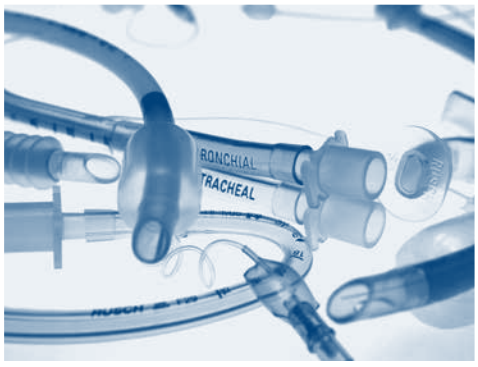
Additional information about the Monitoring Kits see chapter 3.2; page 12

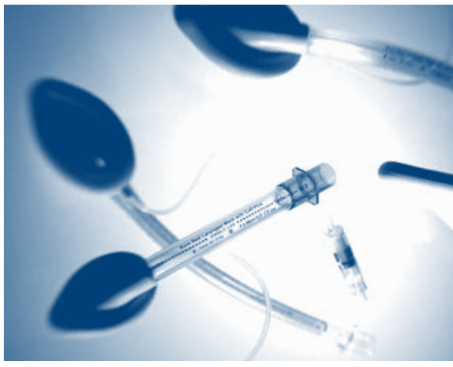
PiCCO Catheter		Monitoring Kit	REF	Getinge order #
PV2015L20-A **6885049** Ø: 5 French Usable length: 20 cm	+	**PV8215 / 6882817** Pressure transducer & 150 cm Arterial Pressure Line; Injectate Temperature Sensor Housing (6882773)	PVPK2015L20-A 5 pieces	6885060 1 purchase unit
PV2013L07-A **6885044** 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

TELEFLEX AIRWAYS

A solid tradition in innovation







Teleflex

TELEFLEX AIRWAY MANAGEMENT – A SOLID TRADITION IN INNOVATION

Trusted brands make Teleflex a reliable and strong partner. Built on a solid tradition of innovation, Teleflex is a global leader in superior medical supplies designed to help providers minimise risk and maximise outcomes for their patients. Our understanding of the importance to our customers of a full range of products has led to the development of a unique line of medical devices, all of which complement one another.

Every article supplied by the Teleflex brands RÜSCH, HUDSON RCI, GIBECK and SHERIDAN is the result of many years of manufacturing experience, specialisation, as well as cooperation with well-known medical experts. Our primary concern is to offer you products of constant quality & unparalleled performance in the field of airway management, to help you focus on what's most important: your patient.

You can find further details and the technical specifications of our products within this brochure.

TELEFLEX – HIGH QUALITY MEDICAL SUPPLIES FROM A SINGLE SOURCE

PAEDIATRIC SIZES AVAILABLE

To meet the special requirements of paediatric care, Teleflex supplies a large variety of tracheal and bronchial tubes. Frequently used models also come in smaller sizes.

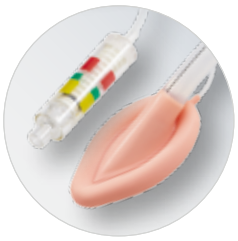
SINGLE USE PRODUCT

DEHP-FREE

To increase patient safety, Teleflex supplies a range of products that does not contain DEHP.

All stated sizes are for information only. Slight variances are possible.




RÜSCH ENDOTRACHEAL TUBES

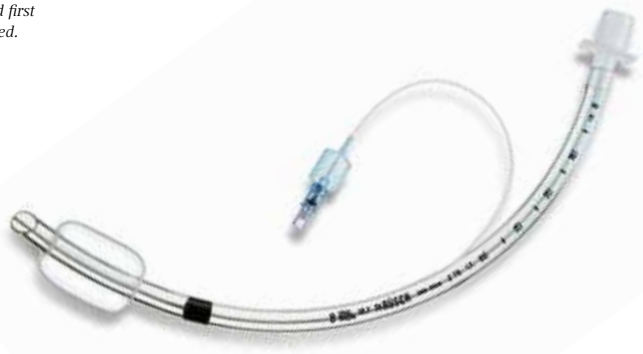
The optimum tube for all applications. At RÜSCH, this demand is met thanks to an extraordinarily extensive and versatile range of tubes. All RÜSCH tubes feature an outstanding I.D. to O.D. ratio. Our high quality standards are reflected in the high-grade materials we use, which are tested according to 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
2.–5.	4.0–5.0 mm	30/40 mm
6.–14.	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 reinserting it.*
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

CLEAR TRACHEAL TUBE MADE OF 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

- latex-free
- sterile

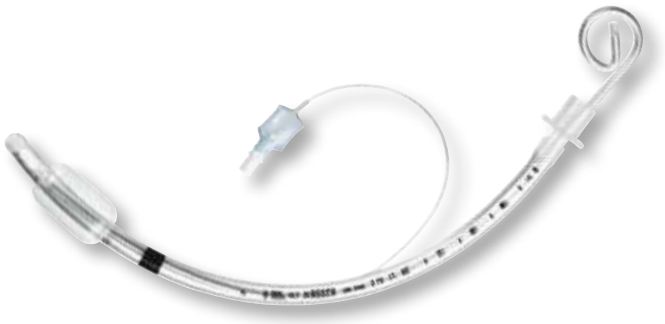
112482,
Murphy, 1 eye

SUPER SAFETYCLEAR — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	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	
	5.0 mm	6.7 mm	13.0 mm	250 mm	
	5.5 mm	7.3 mm	16.5 mm	280 mm	
	6.0 mm	8.0 mm	18.5 mm	290 mm	
	6.5 mm	8.7 mm	20.5 mm	300 mm	
	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*

FLEXISET



SUPER SAFETYCLEAR TRACHEAL TUBE WITH MURPHY EYE AND FLEXISLIP INTUBATION STYLET
sizes: I.D. 5.0–9.0 mm

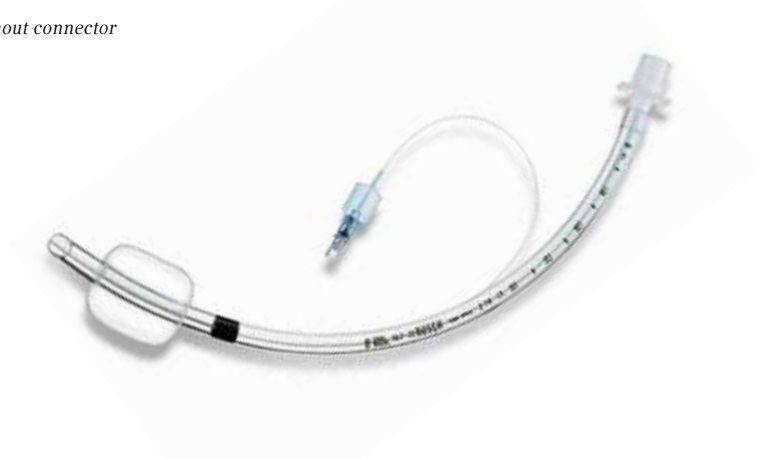
To order each product separately
- Super SafetyClear tracheal tube only, Ref. 112482
- FlexiSlip intubation stylet only, Ref. 503700
(please refer to page 46)

FLEXISET — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
112481	5.0 mm	6.7 mm	13.0 mm	250 mm	10
	5.5 mm	7.3 mm	16.5 mm	280 mm	
	6.0 mm	8.0 mm	18.5 mm	290 mm	
	6.5 mm	8.7 mm	20.5 mm	300 mm	
	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	

** Length without connector*

SAFETYCLEAR PLUS



CLEAR TRACHEAL TUBE MADE OF PVC WITH HIGH-VOLUME LOW-PRESSURE SUPER PLUS CUFF
nasal/oral
sizes: I.D. 5.0–10.0 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

- latex-free
- sterile

SAFETYCLEAR PLUS — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
112080, Magill	5.0 mm	6.7 mm	20 mm	250 mm	10
	5.5 mm	7.3 mm	20 mm	280 mm	
	6.0 mm	8.0 mm	24 mm	290 mm	
	6.5 mm	8.7 mm	24 mm	300 mm	
	7.0 mm	9.3 mm	28 mm	320 mm	
112082, Murphy, 1 eye	7.5 mm	10.0 mm	28 mm	330 mm	
	8.0 mm	10.7 mm	30 mm	340 mm	
	8.5 mm	11.3 mm	30 mm	345 mm	
	9.0 mm	12.0 mm	34 mm	350 mm	
	9.5 mm	12.7 mm	34 mm	350 mm	
	10.0 mm	13.3 mm	34 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

SafetyClear with black tip
in sizes I.D. 2.0–6.5 mm

SAFETYCLEAR — RÜSCH

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	–	

** Length without connector*

ISIS ETT

ENDOTRACHEAL TUBE WITH INTEGRATED PORT FOR OPTIONAL SUBGLOTTIC SECRETION SUCTIONING

The ideal tube to provide the best of care to all your patients, up to 30 days.
nasal/oral 1 eye (Murphy)

Sizes: I.D. 6.0–9.0 mm

This convertible endotracheal tube with separate suction line allows for subglottic secretion removal on demand. This frees the clinician from the burden of deciding for an expensive tube at the time of intubation or to extubate/re-intubate a patient to provide a VAP prevention method of subglottic secretion suctioning. Thanks to the ISIS flexible design, subglottic suctioning can be provided to any patient whenever necessary.

TELEFLEX ISIS ETT

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
112662	6.0 mm	9.2 mm	20.5 mm	290 mm	10
	6.5 mm	9.9 mm	24 mm	300 mm	
	7.0 mm	10.6 mm	26 mm	320 mm	
	7.5 mm	11.3 mm	26 mm	330 mm	
	8.0 mm	12.0 mm	28 mm	340 mm	
	8.5 mm	12.6 mm	28 mm	345 mm	
	9.0 mm	13.2 mm	29 mm	350 mm	

** Length without connector*

Endotracheal tube with integrated port for optional subglottic secretion suctioning.

SUCTION LINE FOR ISIS ENDOTRACHEAL TUBE

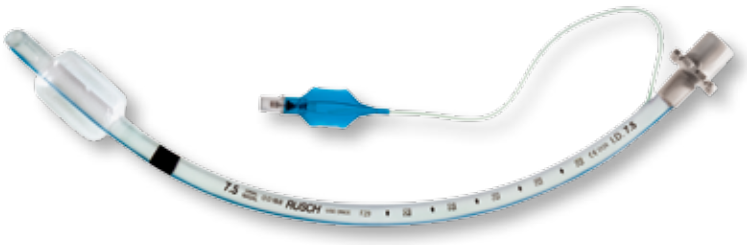
When connected to the ISIS endotracheal tube, the optional suction line provides access from the top of the ETT cuff for easy & safe suctioning of the subglottic secretions that spill over the cuff. Available separately.

1 size fits all ISIS tubes

SUCTION LINE

REF.	QTY
502700	5

SUPER SAFETY SILK



TRACHEAL TUBE MADE OF DEHP-FREE PVC WITH LOW PRESSURE HIGH VOLUME CUFF
nasal/oral
sizes: I.D. 3.0–10.0 mm

tissue-friendly thermosensitive material, especially advantageous for long-term intubation, soft atraumatic tip, continuous X-ray marker, semi-seated connector, low pressure sealing, Safety Silk surface, black ring for intubation depth control

- latex-free
- sterile

SUPER SAFETY SILK — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH	QTY
112682, Murphy, 1 eye sizes: I.D. 3.0–10.0 mm 112680, Magill sizes: I.D. 5.0–10.0 mm	3.0 mm	5.3 mm	8.0 mm	170 mm	10
	3.5 mm	6.0 mm	10.5 mm	190 mm	
	4.0 mm	6.3 mm	10.5 mm	220 mm	
	4.5 mm	6.7 mm	13.0 mm	230 mm	
	5.0 mm	7.3 mm	16.5 mm	250 mm	
	5.5 mm	8.0 mm	18.5 mm	280 mm	
	6.0 mm	8.7 mm	20.5 mm	290 mm	
	6.5 mm	9.3 mm	24.0 mm	300 mm	
	7.0 mm	10.0 mm	26.0 mm	320 mm	
	7.5 mm	10.7 mm	26.0 mm	330 mm	
	8.0 mm	11.6 mm	28.0 mm	340 mm	
	8.5 mm	12.4 mm	28.0 mm	345 mm	
	9.0 mm	13.0 mm	28.0 mm	350 mm	
	9.5 mm	14.2 mm	29.0 mm	350 mm	
	10.0 mm	15.0 mm	29.0 mm	350 mm	

PEDI SAFETY SILK

CLEAR TRACHEAL TUBE
MADE OF SOFT PVC
part of the Safety Silk family,
nasal/oral (Magill)
sizes: I.D. 2.0–5.5 mm

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

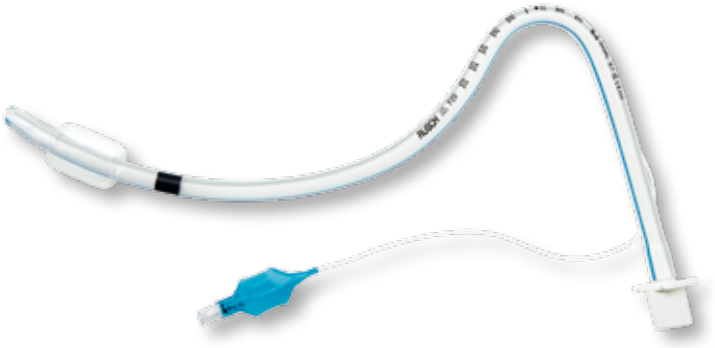
- latex-free
- sterile

PEDI SAFETY SILK — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	BLACK TIP LENGTH	QTY
100480	2.0 mm	3.3 mm	140 mm	20 mm	10
	2.5 mm	4.0 mm	160 mm	20 mm	
	3.0 mm	4.7 mm	180 mm	20 mm	
	3.5 mm	5.3 mm	200 mm	20 mm	
	4.0 mm	6.0 mm	220 mm	30 mm	
	4.5 mm	6.7 mm	240 mm	30 mm	
	5.0 mm	7.3 mm	260 mm	40 mm	
	5.5 mm	8.0 mm	280 mm	40 mm	

** Length without connector*

NASAL SAFETY SILK



CLEAR SOFT ANATOMICALLY SHAPED TUBE
MADE OF DEHP-FREE PVC
nasal only, 1 eye (Murphy)
sizes: I.D. 3.0–8.0 mm

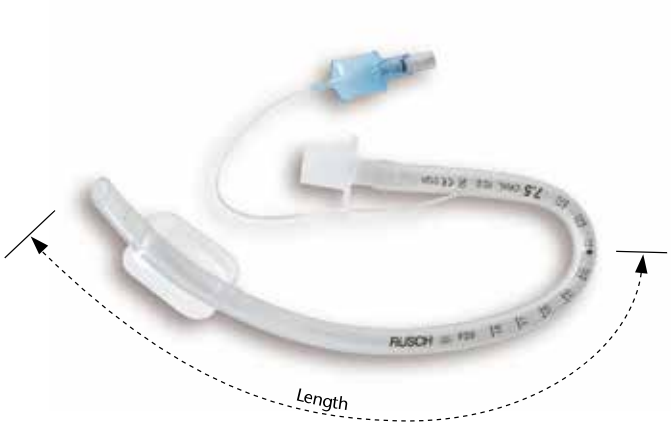
extremely soft & tissue-friendly PVC, bonded connector, kink-resistant, cupped atraumatic tip, continuous blue X-ray marker, graduated, with low-pressure cuff, blue pilot balloon, valve for Luer and Luer-lock syringes

- latex-free
- sterile

NASAL SAFETY SILK — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH	QTY
111782	3.0 mm	5.3 mm	11.0 mm	240 mm	10
	3.5 mm	6.0 mm	11.0 mm	271 mm	
	4.0 mm	6.3 mm	13.0 mm	303 mm	
	4.5 mm	6.7 mm	13.0 mm	338 mm	
	5.0 mm	7.3 mm	16.0 mm	358 mm	
	5.5 mm	8.0 mm	18.0 mm	368 mm	
	6.0 mm	8.7 mm	20.0 mm	415 mm	
	6.5 mm	9.3 mm	24.0 mm	420 mm	
	7.0 mm	10.0 mm	26.0 mm	430 mm	
	7.5 mm	10.7 mm	26.0 mm	445 mm	
	8.0 mm	11.3 mm	28.0 mm	455 mm	

AGT TRACHEAL TUBE ORAL



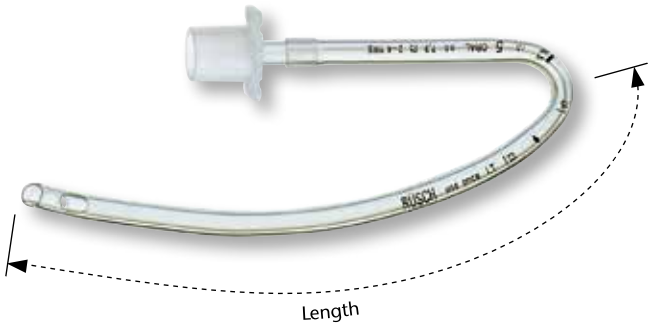
CLEAR ANATOMICALLY SHAPED AGT TUBE MADE OF PVC WITH LOW-PRESSURE CUFF
oral, 1 eye
sizes: I.D. 3.5–9.0 mm

semi-seated connector, cupped atraumatic tip, continuous X-ray marker, graduated, low-pressure cuff, blue pilot balloon, valve for Luer and Luer-lock syringes

- latex-free
- sterile

AGT TRACHEAL TUBE, ORAL RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
111780	3.5 mm	5.3 mm	11 mm	120 mm	10
	4.0 mm	6.0 mm	11 mm	130 mm	
	4.5 mm	6.3 mm	13 mm	145 mm	
	5.0 mm	6.7 mm	13 mm	155 mm	
	5.5 mm	7.3 mm	16 mm	165 mm	
	6.0 mm	8.0 mm	18 mm	180 mm	
	6.5 mm	8.7 mm	20 mm	190 mm	
	7.0 mm	9.3 mm	24 mm	200 mm	
	7.5 mm	10.0 mm	26 mm	210 mm	
	8.0 mm	10.7 mm	26 mm	220 mm	
	8.5 mm	11.3 mm	28 mm	230 mm	
	9.0 mm	12.0 mm	28 mm	240 mm	



CLEAR ANATOMICALLY SHAPED AGT TUBE MADE OF PVC WITHOUT CUFF
oral, 2 eyes
sizes: I.D. 3.0–7.0 mm

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

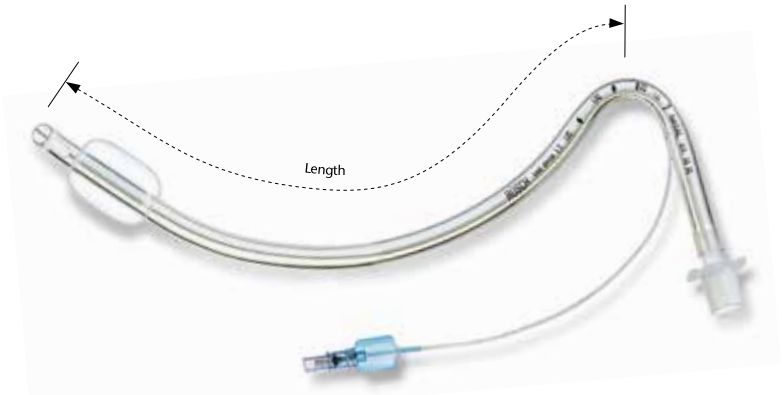
- latex-free
- sterile

AGT TRACHEAL TUBE, ORAL RÜSCH

REF.	ORDER SIZE/ I.D.	O.D.	O.D. (CH.)	LENGTH*	RECOMMENDED SIZE FOR	QTY
100180	3.0 mm	4.0 mm	Ch. 12	105 mm	newborn babies	10
	3.5 mm	4.7 mm	Ch. 14	120 mm	1–6 months	
	4.0 mm	5.3 mm	Ch. 16	130 mm	0.5–1 year	
	4.5 mm	6.0 mm	Ch. 18	145 mm	1–2 years	
	5.0 mm	6.7 mm	Ch. 20	155 mm	2–4 years	
	5.5 mm	7.3 mm	Ch. 22	165 mm	4–6 years	
	6.0 mm	8.0 mm	Ch. 24	180 mm	6–8 years	
	6.5 mm	8.7 mm	Ch. 26	190 mm	8–9 years	
	7.0 mm	9.3 mm	Ch. 28	200 mm	over 9	

** For length see picture*

AGT TRACHEAL TUBE NASAL



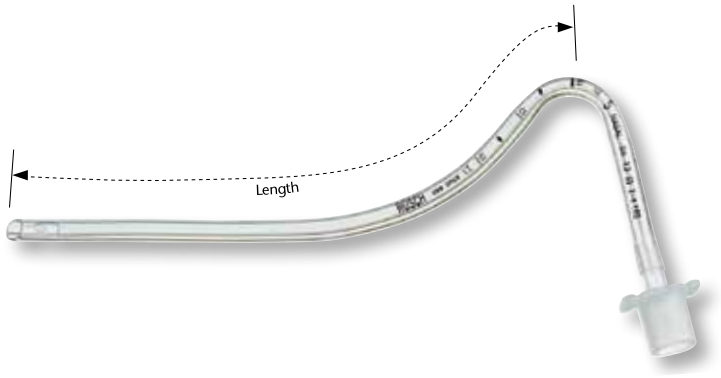
CLEAR ANATOMICALLY SHAPED AGT TUBE MADE OF PVC WITH LOW-PRESSURE CUFF
nasal only, 1 eye
sizes: I.D. 3.5–8.0 mm

semi-seated connector, cupped atraumatic tip, continuous X-ray marker, graduated, low-pressure cuff, blue pilot balloon, valve for Luer and Luer-lock syringes

- latex-free
- sterile

AGT TRACHEAL TUBE, NASAL — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
111781	3.5 mm	5.3 mm	11 mm	160 mm	10
	4.0 mm	6.0 mm	11 mm	185 mm	
	4.5 mm	6.3 mm	13 mm	220 mm	
	5.0 mm	6.7 mm	13 mm	235 mm	
	5.5 mm	7.3 mm	16 mm	245 mm	
	6.0 mm	8.0 mm	18 mm	260 mm	
	6.5 mm	8.7 mm	20 mm	270 mm	
	7.0 mm	9.3 mm	24 mm	280 mm	
	7.5 mm	10.0 mm	26 mm	290 mm	
	8.0 mm	10.7 mm	26 mm	300 mm	



CLEAR ANATOMICALLY SHAPED AGT TUBE MADE OF PVC WITHOUT CUFF
nasal only, 2 eyes
sizes: I.D. 3.0–7.0 mm

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

- latex-free
- sterile

AGT TRACHEAL TUBE, NASAL — RÜSCH

REF.	ORDER SIZE/ I.D.	O.D.	O.D. (CH.)	LENGTH*	RECOMMENDED SIZE FOR	QTY
100181	3.0 mm	4.0 mm	Ch. 12	115 mm	newborn babies	10
	3.5 mm	4.7 mm	Ch. 14	140 mm	1–6 months	
	4.0 mm	5.3 mm	Ch. 16	155 mm	0.5–1 year	
	4.5 mm	6.0 mm	Ch. 18	180 mm	1–2 years	
	5.0 mm	6.7 mm	Ch. 20	190 mm	2–4 years	
	5.5 mm	7.3 mm	Ch. 22	195 mm	4–6 years	
	6.0 mm	8.0 mm	Ch. 24	205 mm	6–8 years	
	6.5 mm	8.7 mm	Ch. 26	210 mm	8–9 years	
	7.0 mm	9.3 mm	Ch. 28	215 mm	over 9	

** For length see picture*

SILKOCLEAR

CLEAR TRACHEAL TUBE MADE OF SILICONE WITH PREFORMED CUFF

nasal/oral, 1 eye (Murphy)
sizes: I.D. 5.0–9.0 mm

fixed connector, valve for Luer and Luer-lock adapter syringes, cupped atraumatic tip, continuous X-ray marker, black position indicator for correct tube placement, transparent pilot balloon, fluted inner lumen, graduated

- latex-free
- sterile

SILKOCLEAR — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
105102	5.0 mm	7.3 mm	8.5 mm	240 mm	5
	5.5 mm	8.0 mm	12.0 mm	270 mm	
	6.0 mm	8.7 mm	12.0 mm	280 mm	
	6.5 mm	9.3 mm	13.5 mm	290 mm	
	7.0 mm	10.0 mm	13.5 mm	300 mm	
	7.5 mm	10.7 mm	13.5 mm	310 mm	
	8.0 mm	11.3 mm	16.0 mm	320 mm	
	8.5 mm	12.0 mm	16.0 mm	330 mm	
	9.0 mm	12.7 mm	16.0 mm	340 mm	

CLEAR TRACHEAL TUBE MADE OF SILICONE WITHOUT CUFF

nasal/oral (Magill)
sizes: I.D. 2.0–4.5 mm

semi-seated connector, black tip, graduated

- latex-free
- sterile

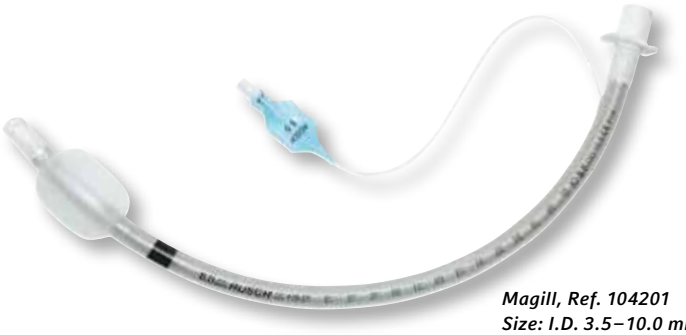
SILKOCLEAR — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	BLACK TIP LENGTH	QTY
100280	2.0 mm	3.3 mm	120 mm	20 mm	10
	2.5 mm	4.0 mm	140 mm	20 mm	
	3.0 mm	4.7 mm	160 mm	20 mm	
	3.5 mm	5.3 mm	180 mm	20 mm	
	4.0 mm	6.0 mm	200 mm	30 mm	
	4.5 mm	6.7 mm	220 mm	30 mm	

** Length without connector*

Please note:
SILKOSPRAY is not suitable for devices made of silicone. If you require a lubricant, we recommend our TrachJell (page 49) or commercially available gels.

RÜSCHFLEX



Magill, Ref. 104201
Size: I.D. 3.5–10.0 mm

Magill, with FlexiSlip,
Ref. 104203
Size: I.D. 5.0–9.0 mm

ARMOURED PREFORMED TRACHEAL TUBE, CURVED, MADE OF PVC WITH LOW-PRESSURE CUFF
nasal/oral
sizes: I.D. 3.5–10.0 mm

fixed white connector, blue pilot balloon, valve for Luer- and Luer-lock syringes, radiopaque, graduated, also available with integrated FlexiSlip stylet (can be ordered separately, Ref. 503700. see page 46 for more details)

- latex-free
- sterile

RÜSCHFLEX RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH* MAGILL 104201/104203	LENGTH* MURPHY 104202/104204	QTY
104201, Magill sizes: I.D. 3.5–10.0 mm 104203, Magill **with FlexiSlip** sizes: I.D. 5.0–9.0 mm	3.5 mm	5.8 mm	228 mm	229 mm	5
	4.0 mm	6.3 mm	235 mm	237 mm	
	4.5 mm	6.8 mm	256 mm	259 mm	
	5.0 mm	7.3 mm	319 mm	321 mm	
	5.5 mm	7.8 mm	319 mm	322 mm	
	6.0 mm	8.4 mm	326 mm	329 mm	
	6.5 mm	9.0 mm	330 mm	334 mm	
	7.0 mm	9.6 mm	349 mm	352 mm	
	7.5 mm	10.2 mm	353 mm	356 mm	
	8.0 mm	10.8 mm	360 mm	364 mm	
	8.5 mm	11.3 mm	384 mm	388 mm	
	9.0 mm	11.9 mm	393 mm	398 mm	
	9.5 mm	12.4 mm	394 mm	399 mm	
	10.0 mm	12.9 mm	395 mm	399 mm	

104202, Murphy, 1 eye
sizes: I.D. 3.5–10.0 mm

104204, Murphy **with FlexiSlip**
sizes: I.D. 5.0–9.0 mm

** Length without connector*

ARMOURED TRACHEAL TUBES

Ref. 104004

ARMOURED TRACHEAL TUBE, STRAIGHT, MADE OF PVC, WITH LOW-PRESSURE CUFF
nasal/oral
sizes: I.D. 5.0–9.0 mm

valve for Luer and Luer-lock syringes, radiopaque, blue pilot balloon, graduated

- latex-free
- sterile

ARMOURED TRACHEAL TUBE — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
104004 fixed white connector	5.0 mm	7.8 mm	17.5 mm	253.0 mm	2
	5.5 mm	8.3 mm	22.0 mm	253.5 mm	
	6.0 mm	8.8 mm	22.0 mm	313.5 mm	
	6.5 mm	9.3 mm	26.5 mm	313.5 mm	
	7.0 mm	9.8 mm	26.5 mm	314.0 mm	
	7.5 mm	10.3 mm	28.5 mm	314.0 mm	
104000 blue mounted connector **FO intubation**	8.0 mm	10.8 mm	28.5 mm	314.0 mm	
	8.5 mm	11.3 mm	29.5 mm	354.0 mm	
	9.0 mm	11.8 mm	29.5 mm	354.5 mm	

Tip:
Ref. 104000 without connector can be used for fibreoptic intubation along with a Mainz universal adaptor (see page 48).

Attention:
We recommend spraying the inside of the tracheal tube and the outside of the suction catheter with SILKOSPRAY (Ref. 556000, see page 49) prior to use.

PAEDIATRIC ARMOURED TRACHEAL TUBE, STRAIGHT, MADE OF PVC, WITHOUT CUFF
nasal/oral
sizes: I.D. 2.5–6.5 mm

mounted connector, radiopaque, graduated

- latex-free
- sterile

PAEDIATRIC ARMOURED TRACHEAL TUBE — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	QTY
103600	2.5 mm	4.1 mm	184.0 mm	2
	3.0 mm	4.8 mm	184.5 mm	
	3.5 mm	5.5 mm	184.5 mm	
	4.0 mm	6.0 mm	194.5 mm	
	4.5 mm	6.5 mm	198.0 mm	
	5.0 mm	7.2 mm	208.0 mm	
	5.5 mm	7.7 mm	208.0 mm	
	6.0 mm	8.2 mm	208.0 mm	
	6.5 mm	8.9 mm	268.5 mm	

* *Length without connector*

SILKOCLEAR FLEX

ARMOURED TRACHEAL TUBE MADE OF SILICONE, WITH HIGHLY FLEXIBLE THIN-WALLED CUFF
nasal/oral, 1 eye (Murphy)
sizes: I.D. 3.5–10.0 mm

fixed connector, valve for Luer and Luer-lock syringes, black position indicator for correct tube placement, pilot balloon, smooth inner tube coating, graduated

- latex-free
- sterile

SILKOCLEAR FLEX — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
105702	3.5 mm	5.0 mm	7.0 mm	226.0 mm	2
	4.0 mm	5.7 mm	7.0 mm	246.0 mm	
	4.5 mm	6.3 mm	7.0 mm	250.5 mm	
	5.0 mm	6.7 mm	8.5 mm	268.0 mm	
	5.5 mm	7.3 mm	12.0 mm	299.0 mm	
	6.0 mm	8.0 mm	12.0 mm	330.5 mm	
	6.5 mm	8.7 mm	12.0 mm	331.0 mm	
	7.0 mm	9.3 mm	13.5 mm	332.0 mm	
	7.5 mm	10.0 mm	13.5 mm	342.5 mm	
	8.0 mm	10.7 mm	16.0 mm	345.5 mm	
	8.5 mm	11.3 mm	16.0 mm	376.0 mm	
	9.0 mm	12.0 mm	16.0 mm	375.0 mm	
	9.5 mm	12.7 mm	18.0 mm	375.5 mm	
	10.0 mm	13.3 mm	18.0 mm	378.0 mm	

PAEDIATRIC ARMOURED TRACHEAL TUBE, STRAIGHT, MADE OF SILICONE, WITHOUT CUFF
nasal/oral
sizes: I.D. 2.0–6.5 mm

fixed connector, cupped atraumatic tip, radiopaque, graduated

- latex-free
- sterile

PAEDIATRIC ARMOURED TRACHEAL TUBE — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	QTY
105400	2.0 mm	3.3 mm	223.0 mm	2
	2.5 mm	3.9 mm	224.0 mm	
	3.0 mm	4.3 mm	225.5 mm	
	3.5 mm	5.0 mm	226.0 mm	
	4.0 mm	5.7 mm	246.0 mm	
	4.5 mm	6.3 mm	250.5 mm	
	5.0 mm	6.7 mm	263.0 mm	
	5.5 mm	7.3 mm	294.5 mm	
	6.0 mm	8.0 mm	326.0 mm	
	6.5 mm	8.7 mm	327.5 mm	

** Length without connector*

Please note: *SILKOSPRAY is not suitable for devices made of silicone. If you require a lubricant, we recommend commercially available gels.*

ARMOURED TRACHEAL TUBE, STRAIGHT, MADE OF SILKOLATEX, WITH SILICONE CUFF
nasal/oral
sizes: I.D. 3.0–10.5 mm
O.D. in CH 18.0–42.0

mounted connector, radiopaque, graduated, with cuff, pilot balloon and universal injection port

- sterile

Tip: *Ref. 103040 without connector can be used for fibreoptic intubation along with a Mainz universal adaptor (see page 48)*
Attention:
These products contain natural rubber latex which may cause allergic reactions.

ARMOURED TRACHEAL TUBE — RÜSCH

REF.	ORDER SIZE	I.D.	O.D.	LENGTH*	QTY
103040	Ch. 18	3.0 mm	6.0 mm	229.0 mm	5
	Ch. 20	3.5 mm	6.7 mm	232.5 mm	
	Ch. 22	4.0 mm	7.3 mm	232.5 mm	
	Ch. 24	5.0 mm	8.0 mm	253.0 mm	
	Ch. 26	5.5 mm	8.7 mm	253.0 mm	
	Ch. 28	6.0 mm	9.3 mm	313.5 mm	
	Ch. 30	6.5 mm	10.0 mm	313.5 mm	
	Ch. 32	7.0 mm	10.7 mm	314.0 mm	
	Ch. 34	8.0 mm	11.3 mm	354.0 mm	
	Ch. 36	8.5 mm	12.0 mm	354.5 mm	
	Ch. 38	9.0 mm	12.7 mm	354.5 mm	
	Ch. 40	9.5 mm	13.3 mm	355.0 mm	
	Ch. 42	10.5 mm	14.0 mm	355.0 mm	

BRONCHOFLEX-SET

ARMOURED TRACHEAL/ INSERTION TUBE MADE OF PVC FOR USE IN BRONCHOSCOPY
(with separate oxygen tubing)
sizes: I.D. 7.5 mm and 8.5 mm

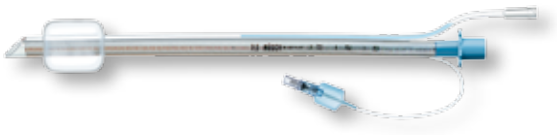
mounted connector, radiopaque, approx. 33 cm long, double lumen, graduated, siliconised, with or without cuff

- latex-free
- sterile

Attention:
We recommend spraying the inside of the bronchial tube and the outside of the suction catheter with SILKOSPRAY (Ref. 556000, see p. 49) prior to use.

BRONCHOFLEX-SET — RÜSCH

REF.	ORDER SIZE/I.D.	TOTAL O.D.	LENGTH*	QTY
104100	7.5 mm	13.8 mm	319 mm	1
	SET COMPONENTS • armoured tracheal/insertion tube made of PVC • oxygen tubing made of PVC, approx. 110 cm long • plastic bite block with fixation flange • neck band			

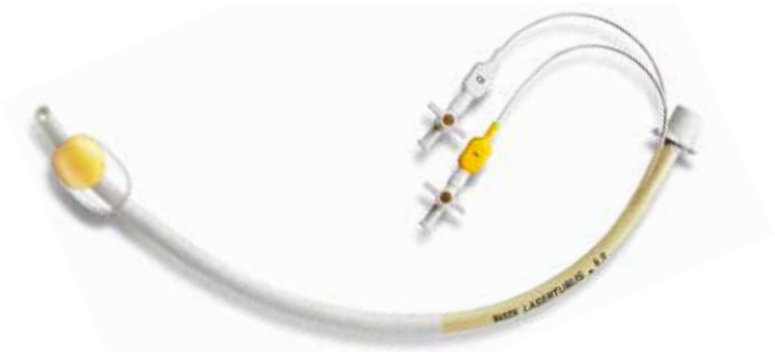


BRONCHOFLEX-SET — RÜSCH

REF.	ORDER SIZE/I.D.	TOTAL O.D.	LENGTH*	QTY
104103	8.5 mm	11.7 mm	359 mm	1
	SET COMPONENTS • armoured tracheal/insertion tube made of PVC with high-volume low-pressure cuff • oxygen tubing made of PVC, approx. 110 cm long • valve for Luer-lock syringes • neckband			

** Length without connector*

LASER TUBE



PREFORMED TRACHEAL TUBE WITH DEFINED LASER-RESISTANCE MADE OF WHITE SOFT RUBBER FOR LASER INTERVENTION IN THE LARYNGEAL SPACE

oral/nasal (Magill), 1 eye (Murphy)
sizes: I.D. 4.0–8.0 mm

fixed white connector, two-way stop-cocks with Luer and Luer-lock adapter and locking mechanism, cupped atraumatic tip, two cuffs inside one another, two pilot balloons, non-kinking shaft, Laserguard film 17 cm long consisting of Merocel® foam and corrugated silver foil

- sterile

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

LASER TUBE RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø OUTSIDE	CUFF Ø INSIDE	LENGTH*	QTY
102004*	4.0 mm	8.0 mm	20 mm	20 mm	400 mm	2
	5.0 mm	9.0 mm	20 mm	20 mm	400 mm	
	6.0 mm	10.8 mm	24 mm	24 mm	400 mm	
	7.0 mm	12.3 mm	28 mm	28 mm	400 mm	
	8.0 mm	13.4 mm	28 mm	28 mm	400 mm	

** Length without connector*

CLEAR MICROLARYNGEAL TUBE

MADE OF PVC WITH HIGH-VOLUME LOW-PRESSURE CUFF
oral/nasal
sizes: I.D. 4.0–6.0 mm
thinner tube body designed for interventions in the laryngeal space

semi-seated connector, valve for Luer and Luer-lock syringes, continuous X-ray marker, blue pilot balloon, graduated

- latex-free
- sterile

MICROLARYNGEAL TUBE — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
112460	4.0 mm	6.0 mm	31 mm	360 mm	10
	5.0 mm	7.3 mm	31 mm	360 mm	
	6.0 mm	8.7 mm	31 mm	360 mm	

** Length without connector*

OXFORD TUBE

CLEAR ANATOMICALLY SHAPED NON-KINKING TUBE MADE OF PVC WITH LOW-PRESSURE CUFF
sizes: I.D. 7.0–10.0 mm

semi-seated connector, valve for Luer and Luer-lock syringes, atraumatic tip, continuous X-ray marker, blue pilot balloon, graduated

- latex-free
- sterile

OXFORD TUBE — RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
112880	7.0 mm	10.0 mm	26 mm	229.5 mm	10
	8.0 mm	11.3 mm	28 mm	237.0 mm	
	9.0 mm	12.7 mm	29 mm	243.5 mm	
	10.0 mm	14.0 mm	29 mm	250.5 mm	

SOFT RUBBER TRACHEAL TUBE

MADE OF SOFT RED RUBBER, WITH CUFF
Magill
sizes: I.D. 2.5–11.0 mm

semi-coated with SILKOLATEX®, cuff and pilot balloon made of SILKOLATEX®, universal injection port, graduated

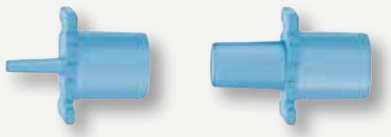
- suitable for MRT
- without metal

Attention:
These products contain natural rubber latex which may cause allergic reactions

SOFT RUBBER TRACHEAL TUBE RÜSCH

REF.	ORDER SIZE/I.D.	O.D.	LENGTH*	QTY
102000	2.5 mm	4.0 mm	140 mm	10
	3.0 mm	4.7 mm	160 mm	
	3.5 mm	5.3 mm	180 mm	
	4.0 mm	6.0 mm	200 mm	
	4.5 mm	6.7 mm	220 mm	
	5.0 mm	7.3 mm	240 mm	
	5.5 mm	8.0 mm	270 mm	
	6.0 mm	8.7 mm	280 mm	
	6.5 mm	9.3 mm	290 mm	
	7.0 mm	10.0 mm	300 mm	
	7.5 mm	10.7 mm	310 mm	
	8.0 mm	11.3 mm	320 mm	
	8.5 mm	12.0 mm	330 mm	
	9.0 mm	12.7 mm	340 mm	
	9.5 mm	13.3 mm	350 mm	
	10.0 mm	14.0 mm	360 mm	
	10.5 mm	14.7 mm	360 mm	
	11.0 mm	15.3 mm	360 mm	

** Length without connector*



STANDARD CONNECTOR RÜSCH

REF.	ORDER SIZE/I.D.	DESCRIPTION	QTY
501003	1.5 mm–11.0 mm	made of plastic, latex-free, 15 mm connection (O.D.)	10

AID INSTILLATION CATHETER

FOR DRUG INSTILLATION DURING CPR AND SURFACTANT APPLICATION IN NEONATOLOGY

with sealable Luer-lock adapter, multiple perforations over a length of 1 cm, opening 1 cm from distal end of the catheter, with intubation stylet, graduated

- latex-free
- sterile

AID ADAPTER SET RÜSCH

REF.	SIZE/O.D.	DESCRIPTION	QTY
111100	Ch. 4	catheter with angled connector	1
	SET COMPONENTS • AID instillation catheter • angled plastic connector		

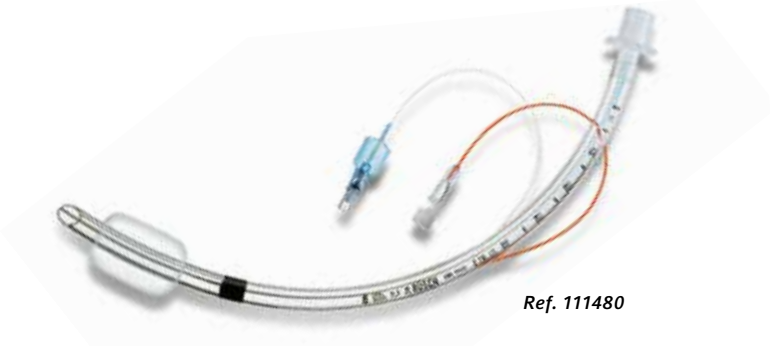
EDGAR TUBE

CLEAR TRACHEAL TUBE MADE OF PVC FOR ENDO-BRONCHIAL DRUG & GAS APPLICATION DURING RESUSCITATION
nasal/oral (Magill)

semi-seated connector, additional instillation channel with sealable Luer-lock adapter, continuous X-ray marker, graduated

Ref. 111480
sizes: I.D. 6.5–10.0 mm
with low-pressure cuff, valve for Luer and Luer-lock syringes and black position indicator for correct tube placement
Ref. 111380
sizes: I.D. 2.5–6.0 mm
without cuff, with black tip

- latex-free
- sterile



Ref. 111480

EDGAR TUBE RÜSCH

REF	ORDER SIZE/I.D.	O.D.	CUFF Ø	LENGTH*	QTY
111480	6.5 mm	9.3 mm	24 mm	290 mm	10
	7.0 mm	10.0 mm	26 mm	300 mm	
	7.5 mm	10.7 mm	26 mm	310 mm	
	8.0 mm	11.3 mm	28 mm	320 mm	
	8.5 mm	12.0 mm	28 mm	330 mm	
	9.0 mm	12.7 mm	29 mm	340 mm	
	9.5 mm	13.3 mm	29 mm	350 mm	
	10.0 mm	14.0 mm	29 mm	360 mm	
111380	2.5 mm	4.0 mm	–	140 mm	10
	3.0 mm	4.7 mm	–	160 mm	
	3.5 mm	5.3 mm	–	180 mm	
	4.0 mm	6.0 mm	–	200 mm	
	4.5 mm	6.7 mm	–	220 mm	
	5.0 mm	7.3 mm	–	240 mm	
	5.5 mm	8.0 mm	–	270 mm	
	6.0 mm	8.7 mm	–	280 mm	

** Length without connector*

SHERIDAN ENDOTRACHEAL TUBES

Supplied under the SHERIDAN brand name, our endo-tracheal tubes offer all the features needed by today's health-care professionals, including a high level of tactile feed-back from the pilot balloon, thermosensitive PVC, which allows the tubes to soften at body temperature, as well as a smooth tube tip that is moulded and gently cupped to minimise trauma during intubation.

SHERIDAN ISIS HVT

ENDOTRACHEAL TUBE WITH INTEGRATED PORT FOR OPTIONAL SUBGLOTTIC SECRETION SUCTIONING WITH HIGH VOLUME TAPERED CUFF
nasal/oral, 1 eye (Murphy)

The ideal tube to provide the best of care to all your patients, both over the short- & long-term.
The unique convertible nature of the Teleflex ISIS HVT frees clinicians from the burden of choosing which tube is best for the patient at the time of intu-bation. ISIS features an integrated suction port and separate suction line allowing for subglottic secretion removal whenever necessary. Both connection ports can be sealed upon disconnection, reducing the risk of cross-contamination when not in use. When needed, the suction tube attaches to the ISIS HVT via a secure locking connection.

- sterile

SHERIDAN ISIS HVT

REF.	ORDER SIZE/I.D.	QTY
5-13012	6.0 mm	10
5-13013	6.5 mm	
5-13014	7.0 mm	
5-13015	7.5 mm	
5-13016	8.0 mm	
5-13017	8.5 mm	
5-13018	9.0 mm	

SUCTION LINE

REF.	QTY
5-23000	5

SHERIDAN/HVT® TRACHEAL TUBE

SHERIDAN/HVT TRACHEAL TUBE		SHERIDAN
REF.	ORDER SIZE/I.D.	QTY
5-10310	5.0 mm	10
5-10311	5.5 mm	
5-10312	6.0 mm	
5-10313	6.5 mm	
5-10314	7.0 mm	
5-10315	7.5 mm	
5-10316	8.0 mm	
5-10317	8.5 mm	
5-10318	9.0 mm	
5-10320	10.0 mm	

HIGH-VOLUME TAPERED, LOW-PRESSURE CUFF
nasal/oral, 1 eye (Murphy)

The high-volume, large diameter cuff provides a positive tracheal wallseal, while the low-pressure cuff minimises capillary restriction. The tapered cuff reduces the risk of micro-aspiration, increases ease of use & minimises the risk of herniation.

- sterile

SHERIDAN/CF® TRACHEAL TUBE

SHERIDAN/CF TRACHEAL TUBE				SHERIDAN
REF.	ORDER SIZE/I.D.	REF.	ORDER SIZE/I.D.	QTY
CF Magill Type		CF Murphy Eye		10
5-10206	3.0 mm	5-10106	3.0 mm	
	-	5-10107	3.5 mm	
5-10208	4.0 mm	5-10108	4.0 mm	
	-	5-10109	4.5 mm	
5-10210	5.0 mm	5-10110	5.0 mm	
	-	5-10111	5.5 mm	
5-10212	6.0 mm	5-10112	6.0 mm	
5-10213	6.5 mm	5-10113	6.5 mm	
5-10214	7.0 mm	5-10114	7.0 mm	
5-10215	7.5 mm	5-10115	7.5 mm	
5-10216	8.0 mm	5-10116	8.0 mm	
5-10217	8.5 mm	5-10117	8.5 mm	
5-10218	9.0 mm	5-10118	9.0 mm	
5-10219	9.5 mm	5-10119	9.5 mm	
5-10220	10.0 mm	5-10120	10.0 mm	

CLOSE FITTING, LOW-PRESSURE CUFF
nasal/oral, 1 eye (Murphy or Magill)

By providing ease of intubation and increasing visualisation, the opaque, close fitting, low- pressure cuff is ideal for short-term surgical intubations.

- sterile

SHERIDAN UNCUFFED™ TRACHEAL TUBE

SHERIDAN UNCUFFED TRACHEAL TUBE — SHERIDAN

REF.	ORDER SIZE/I.D.	QTY
5-10404	2.0 mm	10
5-10405	2.5 mm	
5-10406	3.0 mm	
5-10407	3.5 mm	
5-10408	4.0 mm	
5-10409	4.5 mm	
5-10410	5.0 mm	
5-10411	5.5 mm	
5-10412	6.0 mm	
5-10413	6.5 mm	
5-10414	7.0 mm	

MADE OF PVC, WITHOUT CUFF
nasal/oral, 1 eye (Murphy)
cut on (*) for oral use

Special depth lines at the distal tip indicate the depth of intubation below the chords. The smooth, moulded, gently cupped tip minimises trauma during intubation, while the tube softens at body temperature to conform to the airway anatomy.

- sterile

SHERIDAN PED-SOFT™ UNCUFFED TRACHEAL TUBE

SHERIDAN PED-SOFT UNCUFFED TRACHEAL TUBE — SHERIDAN

REF.	ORDER SIZE/I.D.	DISTAL TIP TO END OF MARK	QTY
5-30404	2.0 mm	20 mm	10
5-30405	2.5 mm	22 mm	
5-30406	3.0 mm	24 mm	
5-30407	3.5 mm	26 mm	
5-30408	4.0 mm	28 mm	
5-30409	4.5 mm	30 mm	
5-30410	5.0 mm	32 mm	
5-30411	5.5 mm	34 mm	
5-30412	6.0 mm	36 mm	
5-30413	6.5 mm	39 mm	
5-30414	7.0 mm	41 mm	

MADE OF PVC, WITHOUT CUFF
nasal/oral, 1 eye (Murphy)

Made of soft PVC, the tube conforms to a child's anatomy. Furthermore, a well defined mark at the distal tip serves as reference point during intubation. Additional depth marks assist in placement during nasal intubation, while the smooth moulded, gently cupped tip minimises trauma during intubation.

- sterile

SHERIDAN PREFORMED™ TRACHEAL TUBE

HIGH-VOLUME TAPERED, LOW-PRESSURE CUFF
nasal/oral, 1 eye (Murphy) with cuffed version
nasal/oral, 2 eyes (Murphy) with uncuffed version

Sheridan Preformed Tracheal Tubes for oral and maxillofacial surgery allow the anaesthesia circuit connection to be positioned out of the surgical field.

Features include: bold marks at the center of the bend with distance to distal tip indicated, high-volume, large diameter cuff for positive tracheal wall seal, low-pressure cuff to minimise capillary restrictions.

Uncuffed tracheal tubes have two Murphy eyes for enhanced patient safety.

- sterile

SHERIDAN PREFORMED TRACHEAL TUBE, ORAL

SHERIDAN

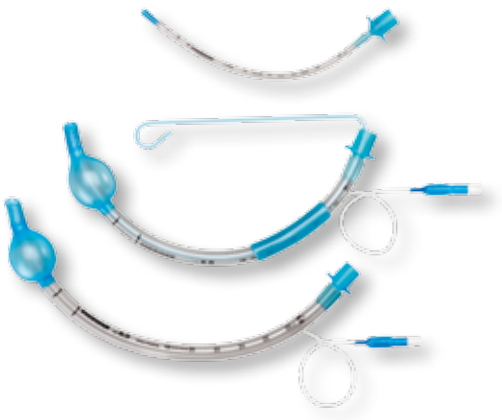
REF.	ORDER SIZE/I.D.	REF.	ORDER SIZE/I.D.	QTY
Uncuffed oral		Cuffed oral		10
5-22006	3.0 mm		-	
5-22007	3.5 mm		-	
5-22008	4.0 mm	5-22208	4.0 mm	
5-22009	4.5 mm	5-22209	4.5 mm	
5-22010	5.0 mm	5-22210	5.0 mm	
5-22011	5.5 mm	5-22211	5.5 mm	
5-22012	6.0 mm	5-22212	6.0 mm	
5-22013	6.5 mm	5-22213	6.5 mm	
5-22014	7.0 mm	5-22214	7.0 mm	
		5-22215	7.5 mm	
		5-22216	8.0 mm	
		5-22217	8.5 mm	
		5-22218	9.0 mm	

SHERIDAN PREFORMED TRACHEAL TUBE, NASAL

SHERIDAN

REF.	ORDER SIZE/I.D.	REF.	ORDER SIZE/I.D.	QTY
Uncuffed nasal		Cuffed nasal		10
5-22106	3.0 mm		-	
5-22107	3.5 mm		-	
5-22108	4.0 mm		-	
5-22109	4.5 mm		-	
5-22110	5.0 mm		-	
5-22111	5.5 mm		-	
5-22112	6.0 mm	5-22312	6.0 mm	
5-22113	6.5 mm	5-22313	6.5 mm	
5-22114	7.0 mm	5-22314	7.0 mm	
		5-22315	7.5 mm	
		5-22316	8.0 mm	

SPIRAL-FLEX REINFORCED TRACHEAL TUBE



HIGH-VOLUME TAPERED, LOW-PRESSURE CUFF
nasal/oral, with cuffed version
nasal/oral, 1 eye (Murphy) with uncuffed version

reduced risk of kinking due to stainless steel, spiral wound reinforcing wire within the tube wall; 15 mm connector is permanently bonded within the tube, blue cuff

- sterile

CUFFED ORAL
cuffed, oral precut length with reinforcing sleeve to minimise the risk of patient biting and occluding the tube; the oral length tube has a reinserted SHER-I-SLIP stylet.

SPIRAL-FLEX REINFORCED TRACHEAL TUBE — SHERIDAN

REF.	ORDER SIZE/I.D.	REF.	ORDER SIZE/I.D.	REF.	ORDER SIZE/I.D.	QTY
Cuffed oral		Cuffed oral/nasal		Uncuffed oral/nasal		5
	-		-	5-12906	3.0 mm	
	-		-	5-12907	3.5 mm	
	-		-	5-12908	4.0 mm	
	-		-	5-12909	4.5 mm	
5-12510	5.0 mm	5-12610	5.0 mm	5-12910	5.0 mm	
5-12511	5.5 mm	5-12611	5.5 mm		-	
5-12512	6.0 mm	5-12612	6.0 mm		-	
5-12513	6.5 mm	5-12613	6.5 mm		-	
5-12514	7.0 mm	5-12614	7.0 mm		-	
5-12515	7.5 mm	5-12615	7.5 mm		-	
5-12516	8.0 mm	5-12616	8.0 mm		-	
5-12517	8.5 mm	5-12617	8.5 mm		-	
5-12518	9.0 mm	5-12618	9.0 mm		-	

LITA CUFFED TRACHEAL TUBE

HIGH-VOLUME TAPERED, LOW-PRESSURE CUFF FOR LARYNGO-TRACHEAL INSTILLATION OF TOPICAL ANAESTHETIC

nasal/oral, 1 eye (Murphy)

allows for spray application of topical anaesthetic via specially designed lumen; patient tolerance of endotracheal tube is increased after administration of topical anaesthesia; black reference bar indicates the position of the uppermost opening

- sterile
- individually packed

LITA CUFFED TRACHEAL TUBE — SHERIDAN

REF.	ORDER SIZE/I.D.	QTY
5-20512	6.0 mm	10
5-20513	6.5 mm	
5-20514	7.0 mm	
5-20515	7.5 mm	
5-20516	8.0 mm	
5-20517	8.5 mm	

SHERIDAN LTS™

TRACHEAL TUBE FOR MICROLARYNGEAL TRACHEAL SURGERY

nasal/oral, 1 eye (Murphy)

small O.D. tube allows greater access to the surgical field, yet provides sufficient ventilation of the patient; same tube length and cuff diameter as an 8.0 mm cuffed tracheal tube; high-volume, yellow cuff is more visible and provides a low-pressure tracheal wall seal

- sterile
- individually packed

SHERIDAN LTS — SHERIDAN

REF.	ORDER SIZE/I.D.	SIZE/O.D.	QTY
5-11108	4.0 mm	5.8 mm	10
5-11110	5.0 mm	7.1 mm	
5-11112	6.0 mm	8.5 mm	

LARYNGEAL MASKS

The true benefits of laryngeal masks are firstly that they lead to less pain and coughing than endotracheal tubes, and secondly, that they can be inserted almost blindly. As such laryngeal masks are used for airway management in both anaesthesia and emergency medicine. Thanks to their soft, thin-walled cuff, they efficiently help to prevent potential traumas caused by excessive pressure. To top it all off, the Teleflex Sure Seal laryngeal mask features an integrated unique cuff pressure device providing at-a-glance feedback on cuff pressure and alerting you instantly to changes before they affect patient safety.

SURE SEAL & CUFF PILOT™

SURE SEAL combines all the features you would expect to find in a high-quality laryngeal mask. The mask itself is made of 100 % silicone and is finely shaped to perfectly contour the oropharyngeal space without trauma.
The tube is available in both silicone and PVC according to preference.
A reinforced laryngeal mask complements the range.
Our Sure Seal product line is further distinguished by a unique cuff pressure monitoring device that enables you to improve patient care and safety: the Cuff Pilot™ provides constant, at-a-glance, visual information on the pressure in the mask.

Packaging colour coding for the disposable Sure Seal product

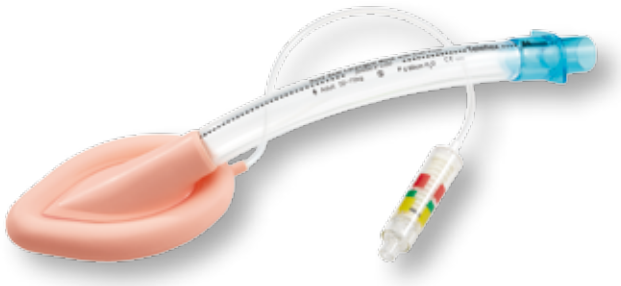
SIZE	1	1.5	2	2.5	3	4	5	6
COLOUR								

The world's first integrated indicator that constantly provides at-a-glance feedback on the pressure inside the cuff, alerting you instantly to changes before they affect patient safety.

SINGLE USE LARYNGEAL MASK WITH CUFF PILOT™

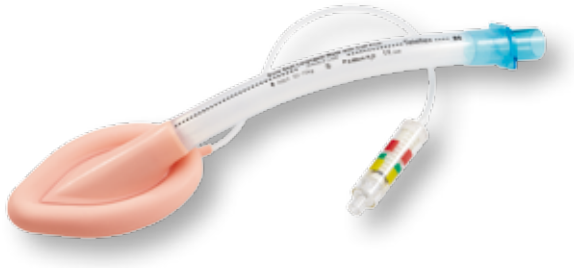
This laryngeal mask offers the advantages of a reusable mask (softness, flexibility), while avoiding the infection risks inherent in resterilization. Furthermore, it provides you with the comfort & safety of the Cuff Pilot.

- latex-free
- sterile



SURE SEAL WITH CUFF PILOT™, SILICONE CUFF & PVC TUBE

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105200	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5



SURE SEAL WITH CUFF PILOT™, 100% SILICONE

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105210	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5

SURE SEAL WITH CUFF PILOT™, 100% SILICONE REINFORCED

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105220	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5

TRACHJELL SINGLE DOSE WATER-SOLUBLE LUBRICANT

To ensure successful intubation, a laryngeal mask needs to be lubricated. Teleflex now provides a water-soluble lubricant, sterile, single-dose, quick & easy to use.

TRACHJELL

REF.	DESCRIPTION	QTY
556100	• water soluble lubricating gel • 8.5 g • sterile	25

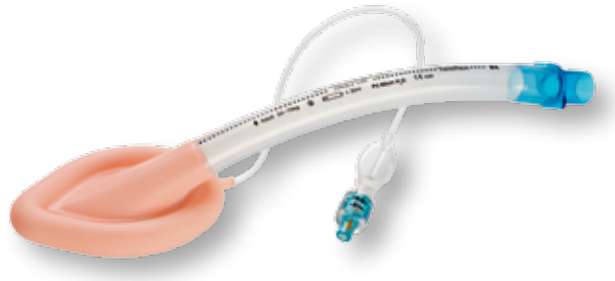
SINGLE USE LARYNGEAL MASK WITH STANDARD PILOT BALLOON

This mask offers you the quality and features you would expect from Teleflex's new range of laryngeal masks. Excellent materials and an outstanding design enable you to concentrate on your patients' breathing rather than on the device.

- latex-free
- sterile

SURE SEAL, SILICONE CUFF & PVC TUBE

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105300	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5



SURE SEAL, 100% SILICONE

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105310	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5

SURE SEAL, 100% SILICONE REINFORCED

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105320	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY	10							5

LARYNGEAL MASKS

SIZE	PATIENT WEIGHT	CUFF MAX VOL.
1.0	< 5 kg	5 ml
1.5	5–10 kg	7 ml
2.0	10–20 kg	10 ml
2.5	20–30 kg	15 ml
3.0	30–50 kg	20 ml
4.0	50–70 kg	35 ml
5.0	70-100 kg	48 ml
6.0	> 100 kg	50 ml

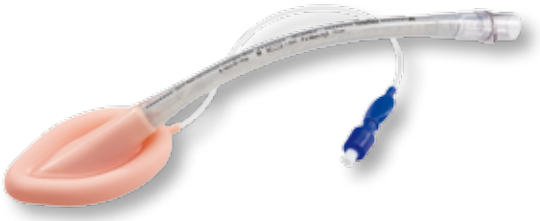
REUSABLE LARYNGEAL MASK WITH STANDARD PILOT BALLOON

Our reusable standard laryngeal mask incorporates everything you need for easy and safe insertion, as well as a reliable seal throughout the procedure.

- latex-free

SURE SEAL, REUSABLE, 100% SILICONE

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105000	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY								2



SURE SEAL, REUSABLE, 100% SILICONE REINFORCED

REF.	SIZE 1	SIZE 1.5	SIZE 2	SIZE 2.5	SIZE 3	SIZE 4	SIZE 5	SIZE 6
105010	-000010	-000015	-000020	-000025	-000030	-000040	-000050	-000060
QTY								2

CRYSTAL AIRWAY MASK®

SINGLE USE LARYNGEAL MASK

Our standard full PVC laryngeal mask

rotationally-moulded cuff with a strong yet thin soft reinforced posterior wall of the cuff, inflation channel integrated into the tube, colour-coded according to size, mask size & patient weight, cuff volume indicated on the tube, black line on the tube for better placement, 15 mm universal connector, 7 sizes

- latex-free
- sterile

CRYSTAL AIRWAY MASK RÜSCH

REF.	SIZE	I.D.	O.D.	COLOUR CODE	QTY
111000	1.0	6.2 mm	8.6 mm	clear	10
	1.5	7.2 mm	10 mm	blue	
	2.0	8.6 mm	12 mm	green	
	2.5	10.4 mm	14 mm	purple	
	3.0	11.0 mm	16 mm	orange	
	4.0	12.4 mm	18 mm	pink	
	5.0	12.4 mm	18 mm	yellow	

RÜSCH BRONCHIAL TUBES AND BLOCKERS

All RÜSCH endobronchial tubes are characterised by high-quality workmanship. They are made of highly flexible and thermoplastic materials. Thanks to special features like the special shape of the bronchial cuff on right-sided models or the extremely soft Carina hook (Carlens and White type), RÜSCH endobronchial tubes are both safe and patient-friendly.

This is particularly true in case of our EZ-Blocker. Thanks to its y-shaped design, this innovative bronchial blocker anchors itself on the carina and will not dislocate following inflation of the isolated lung. After the procedure, when the EZ-Blocker has been removed, there is no need to reintubate the patient.

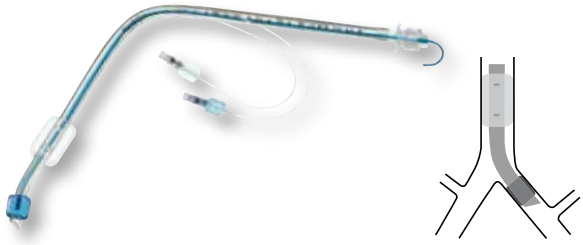
SINGLE-LUMEN BRONCHIAL TUBES

BRONCHIAL TUBE MADE OF PVC

semi-seated connector, valves for Luer and Luer-lock syringes, colourless tracheal low-pressure cuff with colourless pilot balloon, blue bronchial low-pressure cuff with blue pilot balloon, continuous X-ray marker and additional cuff markers, stylet, graduated

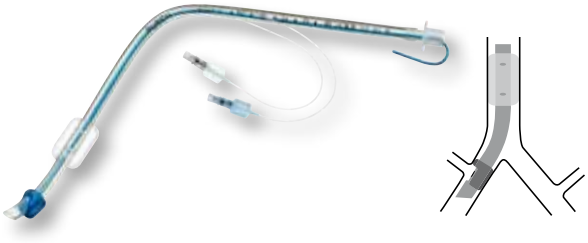
- latex-free
- sterile

ANGLED CONNECTOR
- made of transparent plastic
- double sealing cap made of silicone with small closable opening
- rotating connectors



SINGLE-LUMEN BRONCHIAL TUBE SET — RÜSCH

REF.	ORDER SIZE/I.D.	MAX. O.D.	CUFF Ø BRONCH.	CUFF Ø TRACHEAL	LENGTH*	QTY
115900 (set)	for left-sided bronchial intubation					1
	6.5 mm	9.3 mm	16.5 mm	22±3.3 mm	450 mm	
	8.0 mm	11.3 mm	18 mm	28±4.2 mm	470 mm	
	SET COMPONENTS • single-lumen bronchial tube made of PVC, left • angled connector					



SINGLE-LUMEN BRONCHIAL TUBE SET — RÜSCH

REF.	ORDER SIZE/I.D.	MAX. O.D.	CUFF Ø BRONCH.	CUFF Ø TRACHEAL	LENGTH*	QTY
115901 (set)	for right-sided bronchial intubation					1
	6.5 mm	9.3 mm	16.5 mm	22±3.3 mm	440 mm	
	8.0 mm	11.3 mm	18 mm	28±4.2 mm	460 mm	
	SET COMPONENTS • single-lumen bronchial tube made of PVC, right • angled connector					

** Shaft length*

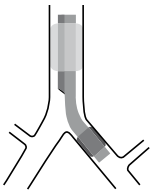
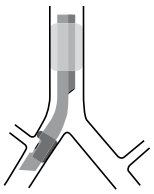
BRONCHOPART

CLEAR DOUBLE-LUMEN BRONCHIAL TUBE MADE OF PVC

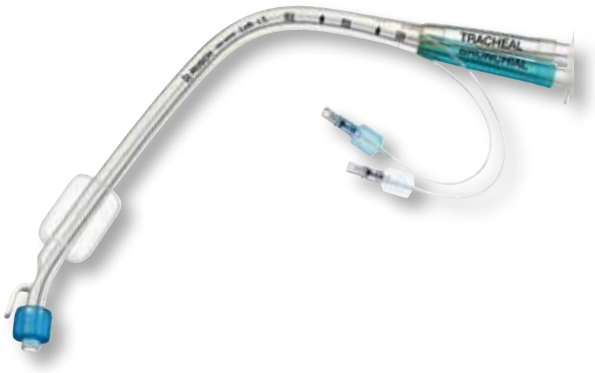
semi-seated connectors, valves for Luer and Luer-lock syringes, continuous X-ray marker and additional cuff markers, colourless tracheal low-pressure cuff with colourless pilot balloon, blue bronchial low-pressure cuff with blue pilot balloon, forming stylet with fixation, graduated

- latex-free
- sterile

BRONCHOPART TUBE SET RÜSCH

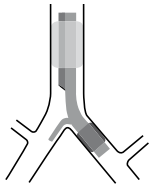
REF.	ORDER SIZE	2 X I.D.	MAX. O.D.	CUFF Ø BRONCH.	CUFF Ø TRACHEAL	LENGTH*	QTY
116100 (set) 116162 (without accessories)	for left-sided bronchial intubation						1
	26	3.40 mm	9.3 mm	15.0 mm	22±3.3 mm	280 mm	
	28	3.71 mm	10.0 mm	15.0 mm	22±3.3 mm	280 mm	
	35	4.26 mm	12.5 mm	16.5 mm	30±4.5 mm	300 mm	
	37	4.52 mm	13.2 mm	16.5 mm	30±4.5 mm	310 mm	
	39	4.76 mm	13.9 mm	18.0 mm	31±4.6 mm	330 mm	
	41	5.04 mm	14.6 mm	18.0 mm	31±4.6 mm	340 mm	
	SET COMPONENTS • double-lumen bronchial tube, left • 2 suction catheters • 2 angled connectors • Y connector						
116200 (set) 116262 (without accessories)	for right-sided bronchial intubation						1
	26	3.40 mm	9.3 mm	15.0 mm	22±3.3 mm	280 mm	
	28	3.71 mm	10.0 mm	15.0 mm	22±3.3 mm	280 mm	
	35	4.26 mm	12.5 mm	16.5 mm	30±4.5 mm	300 mm	
	37	4.52 mm	13.2 mm	16.5 mm	30±4.5 mm	310 mm	
	39	4.76 mm	13.9 mm	18.0 mm	31±4.6 mm	340 mm	
	41	5.04 mm	14.6 mm	18.0 mm	31±4.6 mm	350 mm	
	SET COMPONENTS • double-lumen bronchial tube, right • 2 suction catheters • 2 angled connectors • Y connector						

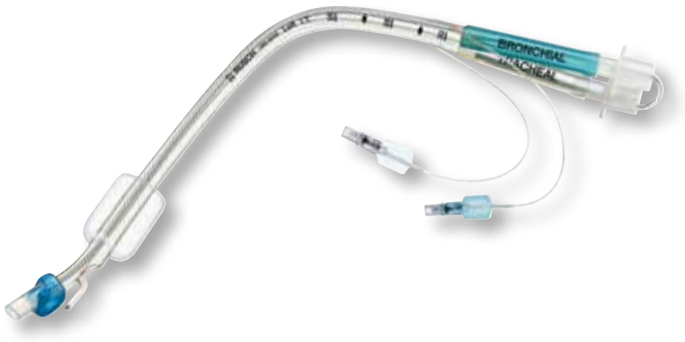
** Shaft length*



BRONCHOPART CARLENS TUBE SET

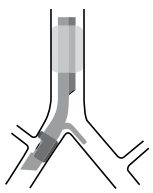
RÜSCH

REF.	ORDER SIZE	2 X I.D.	MAX. O.D.	CUFF Ø BRONCH.	CUFF Ø TRACHEAL	LENGTH*	QTY
116101 (set)	for left-sided bronchial intubation with Carina hook						1
	35	4.26 mm	12.5 mm	16.5 mm	30±4.5 mm	300 mm	
	37	4.52 mm	13.2 mm	16.5 mm	30±4.5 mm	310 mm	
	39	4.76 mm	13.9 mm	18.0 mm	31±4.6 mm	330 mm	
	41	5.04 mm	14.6 mm	18.0 mm	31±4.6 mm	340 mm	
	SET COMPONENTS • Carlens double-lumen bronchial tube, left • 2 suction catheters • 2 angled connectors • Y connector						



BRONCHOPART WHITE TUBE SET

RÜSCH

REF.	ORDER SIZE	2 X I.D.	MAX. O.D.	CUFF Ø BRONCH.	CUFF Ø TRACHEAL	LENGTH*	QTY
116201 (set)	for right-sided bronchial intubation with Carina hook						1
	35	4.26 mm	12.5 mm	16.5 mm	30±4.5 mm	300 mm	
	37	4.52 mm	13.2 mm	16.5 mm	30±4.5 mm	310 mm	
	39	4.76 mm	13.9 mm	18.0 mm	31±4.6 mm	340 mm	
	41	5.04 mm	14.6 mm	18.0 mm	31±4.6 mm	350 mm	
	SET COMPONENTS • White double-lumen bronchial tube, right • 2 suction catheters • 2 angled connectors • Y connector						

** Shaft length*

ACCESSORIES INCLUDED IN SET

SUCTION CATHETER
- made of plastic
- transparent
- with suction control

ANGLED CONNECTORS
- with rotating connectors
- double sealing cap
- standard connectors

Y CONNECTOR
- made of plastic
- 2 x I.D. 15.0 mm
- 1 x O.D. 15.0 mm

NECK BAND
- adjustable (only Tracheopart Ref. 116400/116401)

TRACHEOPART

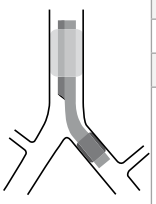
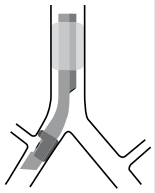
CLEAR DOUBLE-LUMEN TRACHEOSTOMY TUBE MADE OF PVC

semi-seated connectors, valves for Luer and Luer-lock syringes, continuous X-ray marker and additional cuff markers, colourless tracheal low-pressure cuff with colourless pilot balloon, blue bronchial low-pressure cuff with blue pilot balloon, fixation flange

- latex-free
- sterile

TRACHEOPART TUBE SET

RÜSCH

REF.	ORDER SIZE	2 X I.D.	O.D.	CUFF Ø BRONCH.	CUFF Ø TRACH.	LENGTH*	INTRA. LENGTH**	QTY
116400 (set)	for left-sided bronchial intubation							1
	7.5	4.76 mm	13.9 mm	18 mm	26 mm	180 mm	75 mm	
	8.5	4.76 mm	13.9 mm	18 mm	31±4.6 mm	190 mm	85 mm	
	9.5	4.76 mm	13.9 mm	18 mm	31±4.6 mm	200 mm	95 mm	
	SET COMPONENTS • double-lumen tracheostomy tube made of PVC, left • neck band • 2 suction catheters • 2 angled connectors • Y connector							
116401 (set)	for right-sided bronchial intubation							1
	7.5	4.76 mm	13.9 mm	18 mm	26 mm	190 mm	75 mm	
	8.5	4.76 mm	13.9 mm	18 mm	31±4.6 mm	200 mm	85 mm	
	9.5	4.76 mm	13.9 mm	18 mm	31±4.6 mm	210 mm	95 mm	
	SET COMPONENTS • double-lumen tracheostomy tube made of PVC, right • neck band • 2 suction catheters • 2 angled connectors • Y connector							

** Shaft length* *** Intratracheal limb length*

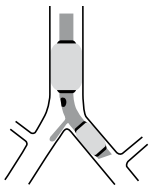
SOFT RUBBER BRONCHIAL TUBES

BRONCHIAL TUBE MADE OF RED SOFT RUBBER

universal injection ports, radiopaque markers, 2 cuffs and 2 pilot balloons made of SILKOLATEX® (red soft rubber coated with SILKOLATEX®)

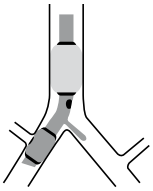
CARLENS TUBE SET

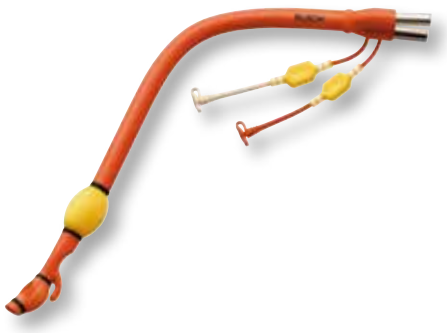
RÜSCH

REF.	ORDER SIZE	2 X I.D.	MAX. O.D.	LENGTH*	QTY
116000 (set)	for left-sided bronchial intubation				1
	35	4.0 mm	11.5 mm	350 mm	
	37	4.7 mm	13.4 mm	365 mm	
	39	4.8 mm	14.3 mm	385 mm	
	41	5.5 mm	15.5 mm	388 mm	
	SET COMPONENTS • Carlens tube made of red soft rubber, left, with Carina hook • suction catheter				

WHITE TUBE SET

RÜSCH

REF.	ORDER SIZE	2 X I.D.	MAX. O.D.	LENGTH*	QTY
116300 (set)	for right-sided bronchial intubation				1
	35	4.0 mm	11.5 mm	350 mm	
	37	4.7 mm	13.4 mm	365 mm	
	39	4.8 mm	14.3 mm	385 mm	
	41	5.5 mm	15.5 mm	388 mm	
	SET COMPONENTS • White tube made of red soft rubber, right, with Carina hook • suction catheter				



** Shaft length*

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

EZ-BLOCKER™ SET

Y-SHAPED BRONCHUS BLOCKER FOR LUNGISOLATION AND ONE-LUNG VENTILATION

- for surgery with fiberoptic or video bronchoscopes
- 75 cm long, exact positioning via an endotracheal tube
- bifurcated distal extensions, both ends with an inflatable cuff and a central lumen, colour coded, minimal risk of dislocation during procedure
- radiopaque shaft with depth markers, cuffs made of polyurethane, providing excellent seal for up to 8 hours
- EZ-Multiport adapter to facilitate ventilation, EZ-Blocker placement and the introduction of fibreoptic or video bronchoscopes and suction catheters
- latex-free
- sterile

EZ-BLOCKER SET RÜSCH

REF.	SET COMPONENTS	LENGTH	SIZE	QTY
MG-02770-002	• 1 EZ-Blocker™ • 1 EZ-Multiport™ adaptor with scope lid • 1 oxygen adaptor • 2 dust caps	75 cm	7 Fr	1

EZ-Blocker combined with ETT (not included in set)

BRONCHUS BLOCKER

MADE OF POLYURETHANE

detachable Luer-lock adapter with valve and stopcock, conical tip with central opening, radiopaque, balloon made of SILKOLATEX® or WIRUPREN®, double-lumen, approx. 170 cm long, graduated

- sterile

Ref. 330600/330601
- for surgery with flexible fibre bronchoscopes with operating channel from I.D. 2.8 mm up
- ideal for use with BronchoFlex (Ref. 1041000, see page 14)

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

BRONCHUS BLOCKER SET RÜSCH

REF.	ORDER SIZE/O.D.	BALLOON CAPACITY	QTY
330600 (set)	Ch. 6	max. 3.0 ml	1
	SET COMPONENTS • bronchus blocker made of polyurethane • single-use syringe 3.0 ml		
330601 (set)	Ch. 6	max. 5.0 ml	1
	SET COMPONENTS • bronchus blocker made of polyurethane • angled connector • single-use syringe 5.0 ml		

Ref. 330602
curved tip for exact positioning in the left or right bronchus via the in situ tracheal tube, high-volume low-pressure cuff, premounted silicone cap for angled connector

- latex-free
- sterile

BRONCHUS BLOCKER SET RÜSCH

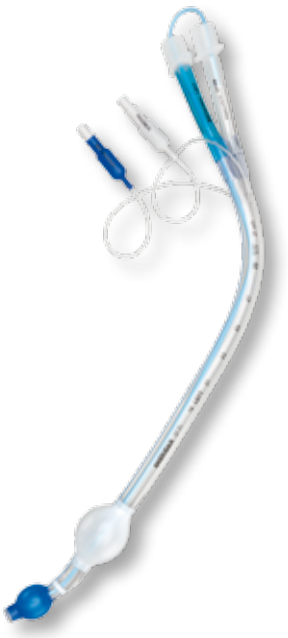
REF.	ORDER SIZE/O.D.	BALLOON CAPACITY	QTY
330602 (set)	Ch. 6	max. 5.0 ml	1
	SET COMPONENTS • bronchus blocker made of polyurethane • angled connector • single-use syringe 5.0 ml		

ANGLED CONNECTOR
- made of plastic
- transparent
- rotating connectors
- double sealing cap with closeable 1.8 mm opening

SINGLE-USE SYRINGE
- 5.0 ml or
- 3.0 ml

SHERIDAN BRONCHIAL TUBES

SHER-I-BRONCH®



LEFT-SIDED DOUBLE LUMEN ENDOBRONCHIAL TUBE FOR INTUBATION OF LEFT MAINSTEM BRONCHUS

colour coding distinguishes bronchial from tracheal airways; radiopaque cuff attachment points and tube tip, full-scale depth marks, blue X-ray line for ease of visualisation during fibreoptic scope insertion, tear-resistant tracheal cuff

- sterile, individually packed

SHER-I-BRONCH® SHERIDAN

REF.	ORDER SIZE	2 X I.D.	QTY
5-16028	28	3.78	1
5-16035	35	4.90	
5-16037	37	5.16	
5-16039	39	5.51	
5-16041	41	5.56	

RIGHT-SIDED DOUBLE LUMEN ENDOBRONCHIAL TUBE FOR INTUBATION OF RIGHT MAINSTEM BRONCHUS

1 large eye (for ventilating right upper lobe bronchial orifice)

unique double cuff design increases the margin of safety, when positioning the tube in the right mainstem bronchus; full-scale depth marks, blue X-ray line for ease of visualisation during fibreoptic scope insertion, tear-resistant tracheal cuff

- sterile, individually packed

SHER-I-BRONCH® SHERIDAN

REF.	ORDER SIZE	2 X I.D.	QTY
5-16128	28	3.78	1
5-16135	35	4.90	
5-16137	37	5.16	
5-16139	39	5.51	
5-16141	41	5.56	

SHER-I-BRONCH® ACCESSORY PACK* SHERIDAN

REF.	DESCRIPTION	QTY
5-16142	SET COMPONENTS: SHER-I-SWIV/FO® double swivel connectors for use with fibreoptic scope, Y connector, and three special length suction catheters	20

** packaged separately with every SHER-I-BRONCH® endobronchial tube*

OROPHARYNGEAL/ NASOPHARYNGEAL AIRWAYS

For quick and safe airway patency without intubation the user can choose from an extensive range of RÜSCH oropharyngeal and nasopharyngeal airways.
All versions have been specifically developed to meet the customer's requirements and thus represent a safe and adequate solution for most indications. RÜSCH offers not only standard versions made from a variety of materials but also special models for endoscopy that offer simultaneous fixation of the tracheal tube. Thanks to the broad selection, these RÜSCH products have become indispensable in many situations.

OROPHARYNGEAL AIRWAYS

OROPHARYNGEAL AIRWAY — RÜSCH

	DESCRIPTION	REF.	ORDER SIZE	ISO SIZE	COLOUR CODE	QTY
	made of PVC • Guedel airway • colour-coded • clear • latex-free	124700	000	3	colourless	10
			00	4	pink	
			0	5	blue	
			1	6	black	
			2	7	white	
			3	8	green	
			4	9	yellow	
			5	10	red	
			6	12	purple	
	made of polyethylene • Guedel airway • colour-coded • latex-free	124900 sterile	000	3	colourless	10
			00	4	pink	
			0	5	blue	
			1	6	black	
			2	7	white	
			3	8	green	
			4	9	yellow	
			5	10	red	
		672901 non-sterile	00	4	pink	50
			0	5	blue	
			1	6	black	
			2	7	white	
			3	8	green	
			4	9	yellow	
			5	10	red	

OROPHARYNGEAL AIRWAYS

RÜSCH

	DESCRIPTION	REF.	ORDER SIZE	ISO SIZE		QTY
	made of soft rubber for fibreoptic intubation • Guedel airway • slit along upper surface	124400*	3	8		2
			4	9		
			5	10		
 *Ref. 124500* *Ref. 124501*	made of soft rubber • Guedel airway	124500* black 124501* red	000	3		10
			00	4		
			0	5		
			1	6		
			2	6.5		
			3	8		
			4	9		
			5	10		
			6	12		

	DESCRIPTION	REF.	ORDER SIZE	I.D.	LENGTH APPROX.	QTY
	OPTOSAFE bite block made of PVC, for fibreoptic intubation • Guedel airway • circular inner diameter • latex-free • sterile	124200	7	7 mm	67 mm	2
			11	11 mm	80 mm	
			13	13 mm	80 mm	
			15	15 mm	95 mm	

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

CATH-GUIDE® AIRWAY

HUDSON RCI

	DESCRIPTION	REF.	ORDER SIZE	I.D.	QTY
	• flexible vinyl with a rigid bite block • Guedel style with three internal channels • available in eight sizes • individually packed	41165	5	120 mm	48
		41166	4	110 mm	
		41167	3	100 mm	
		41164	2	90 mm	
		41168	1	80 mm	
		41169	0	70 mm	
		41170	00	60 mm	
		41171	000	55 mm	

BITEGARD® ORAL BITE BLOCK

HUDSON RCI

	DESCRIPTION	REF.	QTY
	• oral bite block	41140	2

NASOPHARYNGEAL AIRWAYS

NASOPHARYNGEAL AIRWAY, WENDL PATTERN, MADE OF WIRUPREN®

- with adjustable flange
- latex-free
- sterile

NASOPHARYNGEAL AIRWAY, WENDL PATTERN, MADE OF SOFT RUBBER

- with adjustable flange

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

NASOPHARYNGEAL AIRWAY MADE OF PVC

- transparent
- sterile

NASOPHARYNGEAL AIRWAYS — RÜSCH

REF.	ORDER SIZE	I.D.	O.D.	LENGTH	QTY
185420	12	2.0 mm	4.00 mm	95 mm	5
	14	2.5 mm	4.67 mm	95 mm	
	16	3.4 mm	5.33 mm	95 mm	
	18	3.5 mm	6.00 mm	95 mm	
	20	4.5 mm	6.67 mm	125 mm	
	22	5.0 mm	7.33 mm	170 mm	
	24	5.5 mm	8.00 mm	170 mm	
	26	6.0 mm	8.67 mm	170 mm	
	28	6.5 mm	9.33 mm	170 mm	
	30	7.0 mm	10.00 mm	170 mm	
	32	7.5 mm	10.67 mm	170 mm	
	34	8.0 mm	11.33 mm	170 mm	
	36	8.5 mm	12.00 mm	170 mm	
125200	12	2.0 mm	4.0 mm	95 mm	5
	14	2.5 mm	4.7 mm	95 mm	
	16	3.0 mm	5.3 mm	95 mm	
	18	3.5 mm	6.0 mm	95 mm	
	20	4.0 mm	6.7 mm	115 mm	
	22	4.5 mm	7.3 mm	125 mm	
	24	5.0 mm	8.0 mm	170 mm	
	26	5.5 mm	8.7 mm	170 mm	
	28	6.0 mm	9.3 mm	170 mm	
	30	6.5 mm	10.0 mm	170 mm	
	32	7.0 mm	10.7 mm	170 mm	
	34	7.5 mm	11.3 mm	170 mm	
	36	8.0 mm	12.0 mm	170 mm	
125410	12	2.5 mm	3.97 mm	60 mm	10
	14	3.0 mm	4.64 mm	72 mm	
	16	3.5 mm	5.30 mm	85 mm	
	18	4.0 mm	5.97 mm	105 mm	
	19	4.5 mm	6.29 mm	110 mm	
	20	5.0 mm	6.63 mm	115 mm	
	22	5.5 mm	7.29 mm	125 mm	
	24	6.0 mm	7.96 mm	130 mm	
	26	6.5 mm	8.63 mm	140 mm	
	28	7.0 mm	9.29 mm	155 mm	
	30	7.5 mm	9.96 mm	165 mm	
	32	8.0 mm	10.63 mm	170 mm	
	34	8.5 mm	11.29 mm	175 mm	
	36	9.0 mm	11.95 mm	180 mm	

NASOPHARYNGEAL AIRWAY, MADE OF SILKOLATEX® RÜSCH GOLD

- with adjustable flange and widened end
- sterile

NASOPHARYNGEAL AIRWAY, ROBERTAZZI PATTERN, MADE OF WIRUPREN®

- latex-free
- sterile

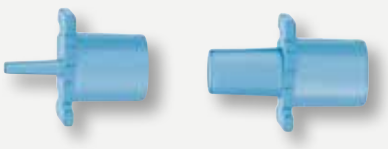
NASOPHARYNGEAL AIRWAY, WENDL PATTERN, MADE OF SOFT RUBBER

- double lumen
- with adjustable flange
- oxygen insufflation tube

NASOPHARYNGEAL AIRWAYS — RÜSCH

REF.	ORDER SIZE	I.D.	O.D.	LENGTH	QTY
185200*	20	4.5 mm	6.7 mm	125 mm	10
	22	5.0 mm	7.3 mm	170 mm	
	24	5.5 mm	8.0 mm	170 mm	
	26	6.0 mm	8.7 mm	170 mm	
	28	6.5 mm	9.3 mm	170 mm	
	30	7.0 mm	10.0 mm	170 mm	
	32	7.5 mm	10.7 mm	170 mm	
	34	8.0 mm	11.3 mm	170 mm	
	36	8.5 mm	12.0 mm	170 mm	
185410	20	3.6 mm	6.67 mm	100 mm	10
	22	4.6 mm	7.33 mm	105 mm	
	24	5.2 mm	8.00 mm	105 mm	
	26	5.8 mm	8.67 mm	110 mm	
	28	6.5 mm	9.33 mm	117 mm	
	30	7.0 mm	10.00 mm	118 mm	
	32	7.6 mm	10.67 mm	140 mm	
	34	7.9 mm	11.33 mm	155 mm	
	36	9.0 mm	12.00 mm	170 mm	
125600*	24	5.5 mm	8.0 mm	160 mm	5
	26	6.0 mm	8.7 mm	160 mm	
	28	6.5 mm	9.3 mm	170 mm	
	30	7.0 mm	10.0 mm	170 mm	
	32	7.6 mm	10.7 mm	170 mm	

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



STANDARD CONNECTOR — RÜSCH

REF.	ORDER SIZE/I.D.	DESCRIPTION	QTY
501003	1.5 mm–11.0 mm	made of plastic, latex-free, 15 mm connection (O.D.)	10

ANAESTHESIA MASKS/ REBREATHING BAGS

We have a long tradition of serving the medical market with tried and tested quality products, and our RÜSCH and HUDSON RCI anaesthesia masks and rebreathing bags are classic examples of these. Whether they are made of silicone, Wirupren or rubber latex, the selection of masks and bags at your disposal meets every requirement. You and your patients can rely on us.

REUSABLE FACE MASKS

SILICONE FACE MASK

- blue
- inflatable
- 22 mm connection
- latex-free

SILICONE FACE MASK — RÜSCH

REF.	ORDER SIZE	QTY
154200	1	1
	2	
	3	

PAEDIATRIC SILICONE FACE MASK

- Rendall-Baker-Soucek pattern
- transparent
- 22 mm connection
- latex-free

PAEDIATRIC SILICONE FACE MASK — RÜSCH

REF.	ORDER SIZE	QTY
154300	0	2
	1	
	2	
	3	

PAEDIATRIC BLACK RUBBER FACE MASK

- Rendall-Baker-Soucek pattern
- black
- 22 mm connection
- size 3 available only with harness ring

PAEDIATRIC BLACK RUBBER FACE MASK — RÜSCH

REF.	ORDER SIZE	QTY
154700*	0	1
	1	
	2	
	3	

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

SILICONE FACE MASK

- Size 0-2: round, transparent
- Size 3-5: anatomically shaped, non-inflatable
- 22 mm connection
- latex-free

size 3–5

size 0–2

SILICONE FACE MASK		RÜSCH
REF.	ORDER SIZE	QTY
154900	0	2
	1	
	2	
	3	
	4	
	5	

BLACK RUBBER FACE MASK

- 154600 without hook ring
- 154601 with hook ring
- inflatable
- 22 mm connection

154600

154601

BLACK RUBBER FACE MASK		RÜSCH
REF.	ORDER SIZE	QTY
154600* 154601* hook ring	0	1
	1	
	2	
	3	
	4	
	5	
	6	

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

SILICONE FACE MASK

- with transparent visual field made of PSU
- inflatable pad
- latex-free

SILICONE FACE MASK		RÜSCH
REF.	ORDER SIZE	QTY
672910	2	1
	3	
	5	

DISPOSABLE FACE MASKS

AIR CUSHION FACE MASK

- single use
- latex-free

CLEAR COMFORT MASK

- sizes 1 to 3: scented
- sizes 3 to 6: 22 mm colour-coded retaining ring, removable for hand-held procedures
- 15 mm connector for sizes 1 & 2
- 22 mm connector for sizes 3 to 6
- single use

AIR CUSHION FACE MASKS — HUDSON RCI

REF.	DESCRIPTION		CONNECTOR	RING COLOUR	QTY
41271	neonate		15 mm	white	20
41272	infant		15 mm	pink	
41273	paediatric/toddler		22 mm	yellow	
41274	small adult/youth		22 mm	green	
41275	medium adult		22 mm	red	
41276	large adult		22 mm	blue	
41277	neonate	with inflation valve	15 mm	white	
41278	infant	with inflation valve	15 mm	pink	
41279	paediatric/toddler	with inflation valve	22 mm	yellow	
41280	small adult/youth	with inflation valve	22 mm	green	
41281	medium adult	with inflation valve	22 mm	red	
41282	large adult	with inflation valve	22 mm	blue	

CLEAR COMFORT MASK WITH INFLATION PORT — RÜSCH

REF.	ORDER SIZE	DESCRIPTION		QTY
415800	1	neonate	Baby powder scent – no ring	20
415802	2	infant	Strawberry scent – no ring	
415804	3	child	Bubblegum scent – yellow ring	
415806	4	small adult	No scent – green ring	
415808	5	medium adult	No scent – red ring	
415810	6	large adult	No scent – blue ring	

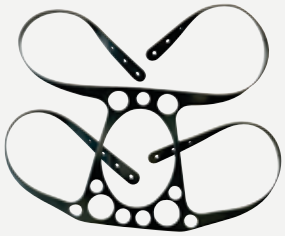
RUBBER BAND TO HOLD FACE MASKS

- black
- conductive

RUBBER BAND — RÜSCH

REF.	QTY
154500*	10

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



RESUSCITATORS

DISPOSABLE LIFESAVER™ RESUSCITATORS

Disposable lifesaver resuscitators from HUDSON RCI combine quality, features, and performance with the convenience of a disposable product. They are designed to meet or exceed ISO and ASTM standards. The unique right-angle oxygen tubing connector swivels 360°. The paediatric and neonate bags have a built-in pressure relief valve and a pressure monitoring port.

- with mask and flow diverter
- individually packed

RESUSCITATORS — HUDSON RCI

REF.	DESCRIPTION	QTY
45372	adult	
45367	paediatric (child)	
45362	neonate (infant)	

PEEP VALVE — HUDSON RCI

REF.		DESCRIPTION	QTY
45385		• adjustable from 5 to 20 cm H_2O • ISO standard 30 mm I.D. connector • individually packed	10

REBREATHING BAGS

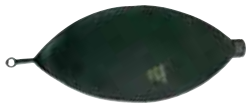
SILKOBAG

RÜSCH

	REF.	ORDER SIZE / VOLUME		DESCRIPTION	QTY
	150700	0.5 l	2.0 l	• made of silicone • with loop • 22 mm connection • latex-free	2
		1.0 l	2.3 l		
		1.5 l	3.0 l		
	150560	0.5 l		• with loop • with hole • 22 mm connection • latex-free	2
		1.5 l			
		2.3 l			

LATEX REBREATHING BAG

RÜSCH

	REF.	ORDER SIZE / VOLUME		DESCRIPTION	QTY
	151000*	0.5 l	2.3 l	• black • with loop • 22 mm connection	5
		1.0 l	3.0 l		
		1.5 l	3.5 l		
		2.0 l	5.0 l		
	151300*	0.5 l	2.3 l	• black • with extended loop • 22 mm connection	5
		0.75 l	3.0 l		
		1.0 l	4.0 l		
		1.5 l	5.0 l		
		2.0 l	6.0 l		
	153000*	2.0 l	2.3 l	• black • with extended closed tube • with loop • 22 mm connection	5
		0.5 l	3.0 l		
		1.0 l	3.5 l		
		1.5 l	5.0 l		

NEOPRENE REBREATHING BAG

RÜSCH

	REF.	ORDER SIZE / VOLUME	DESCRIPTION	QTY
	191670	0.5 l	• green • 22 mm connection • latex-free	10
		1.0 l		
		2.0 l		
		3.0 l		

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

STYLETS

FLEXISLIP INTUBATION STYLET

flexible metal stylet with plastic coating, smooth surface, curved handle

- for tracheal tubes
- cupped, soft tip
- latex-free
- sterile

FLEXISLIP INTUBATION STYLET

REF.	ORDER SIZE	LENGTH CURVED	O.D.	FOR I.D.	QTY
503700	6	220 mm	1.95 mm	2.5 mm	20
	10	335 mm	3.28 mm	3.5 mm	
	12	366 mm	3.93 mm	4.0 mm	
	14	366 mm	4.60 mm	5.0 mm	

INTUBATION STYLET MADE OF PVC

- for tracheal tubes
- flexible
- cupped, soft tip
- latex-free

INTUBATION STYLET MADE OF PVC

RÜSCH

REF.	ORDER SIZE	LENGTH APPROX.	O.D.	FOR I.D.	QTY
503000	15	350 mm	1.5 mm	2.0–2.5 mm	10
	20	400 mm	2.0 mm	2.5–3.0 mm	
	26	400 mm	2.6 mm	3.0–3.5 mm	
	33	450 mm	3.3 mm	3.5–4.5 mm	
	43	450 mm	4.3 mm	4.5–6.0 mm	
	56	500 mm	5.6 mm	ab 6.0 mm	

- for non-kinking (Oxford) tube
- right-angled
- hard
- latex-free

INTUBATION STYLET MADE OF PVC

RÜSCH

REF.	ORDER SIZE	LENGTH APPROX.	O.D.	FOR I.D.	QTY
502900	1	280 mm	2.6 mm	3.5–5.0 mm	5
	2	370 mm	4.3 mm	5.5–6.0 mm	
	3	410 mm	5.6 mm	7.0–12.0 mm	

ENDOGUIDE TUBE EXCHANGER AND INSERTION AID IN ONE

permanently available large lumen for constant oxygenation of the patient; connection system for 15 mm and Luer-lock connectors, depth markers

- latex-free
- sterile

ENDOGUIDE-T

RÜSCH

REF.	ORDER SIZE	I.D.	O.D.	LENGTH*	QTY
503100	2.5	1.4 mm	2.6 mm	700 mm	1
	6.0	3.2 mm	5.0 mm	830 mm	
503110	6.0	3.2 mm	5.0 mm	525 mm	

** Length without connector*

CONNECTOR SET
- Luer-lock connector
- silicone cone
- 15 mm standard connector

SHER-I-SLIP® INTUBATION STYLET

dependable stiffness retains desired curve during oral intubation; blue colour improves visualisation; special material reduces stylet-to-tube friction; smooth moulded distal tip end

SHER-I-SLIP INTUBATION STYLET HUDSON RCI

REF.	LENGTH APPROX.	O.D.	FOR TUBE SIZES I.D.	QTY
5-15101	340 mm	10 Fr	5.0 - 10.0 mm	25
5-15102	250 mm	5 Fr	2.0 - 4.5 mm	
5-15103	X-Long	10 Fr	5.0 - 10.0 mm	

SOFT-TIP™ INTUBATION STYLET

atraumatic tip to minimise trauma; slippery outer finish makes for easy transition into endotracheal tube

SOFT-TIP INTUBATION STYLET HUDSON RCI

REF.	LENGTH APPROX.	O.D.	FOR TUBE SIZES I.D.	QTY
5-15120	270 mm	6 Fr	2.5 - 4.5 mm	20
5-15110	330 mm	10 Fr	4.5 - 6.5 mm	
5-15100	310 mm	14 Fr	6.0 - 10.0 mm	

ACCESSORIES

UNIVERSAL ADAPTER, MAINZ PATTERN

	REF.	DESCRIPTION	QTY
	514800	sizes: O.D. 15.0 mm and 22.0 mm • made of plastic, white • for fibreoptic intubation during simultaneous mask ventilation • connector for face masks • lateral connector for anaesthetic circuit • double sealing cap made of silicone • latex-free • sterile	5
	514805	sizes: O.D. 15.0 mm and 22.0 mm/I.D. 15 mm • made of blue plastic • for fibreoptic intubation during simultaneous mask ventilation • connector for face masks, tracheal tubes and laryngeal masks • lateral connector for anaesthetic circuit • double sealing cap made of silicone • latex-free • sterile	5

SHER-I-SWIV® DOUBLE SWIVEL CONNECTOR

	REF.	DESCRIPTION	QTY
	5-15301	• for use with tracheostomy and tracheal tubes • reduces breathing circuit drag and torque on the tube • strap connector for anti-disconnect security • special swivel joints reduce leakage potential • easy suction catheter passage with secure closure	25

SHER-I-SWIV/FO™ DOUBLE SWIVEL CONNECTOR

	REF.	DESCRIPTION	QTY
	5-15401	• for use with fibreoptics • allows easy passage of fibreoptic scope while maintaining an air-tight seal around scope for positive pressure ventilation	25

DOUBLE SEALING CAP MADE OF SILICONE

	REF.	DESCRIPTION	QTY
	514801	sizes: I.D. 2.0 mm, blue I.D. 3.5 mm, transparent • for universal adapter, Mainz pattern (Ref. 514800/514805) • latex-free • sterile	5

M-CONNECTOR MADE OF PLASTIC

	REF.	DESCRIPTION	QTY
	514700	• m-connector • blue • 2 x O.D. 22 mm • 1 x O.D. 22 mm / I.D. 15 mm, rotating • latex-free	5

MOUTH GAG, MADE OF RED SOFT RUBBER

a) b)

REF.	DESCRIPTION	QTY
610000*	a) blunt-nosed	5
610001*	b) long-tapered	5
	size: 95 x 27 x 18 mm ***Attention*** *These products contain natural rubber latex which may cause allergic reactions.*	

CUFF PROTECTION TUBE

REF.	DESCRIPTION	QTY
502501*	• O.D. 4.0 mm • for nasal insertion of tracheal tubes • length of yellow protection sleeve approx. 7 cm • total length approx. 40 cm • made of PVC/SILKOLATEX® ***Attention*** *These products contain natural rubber latex which may cause allergic reactions.*	5

ENDOTRACHEAL TUBE HOLDER

REF.	DESCRIPTION	QTY
41065	• keeps the endotracheal tube in place • supplied with cloth tie, safety-pin, and soft foam mouth cushion • built-in bite block	10

SINGLE USE MAGILL FORCEPS

REF.	DESCRIPTION	QTY
503300-000150	infant	10
503300-000200	child	10
503300-000245	adult	10

ENDOTEST

REF.	DESCRIPTION	QTY
112700	device for filling and monitoring the pressure of low-pressure cuffs on tracheal, tracheostomy, bronchial tubes and laryngeal masks • with connecting tube	1
230100	connecting tube made of PVC for ENDOTEST cuff pressure monitoring device • transparent • with Luer-connector (male and female) • approx. 100 cm long, 2 x 3 mm • latex-free • sterile	10

SILKOSPRAY

REF.	DESCRIPTION	QTY
556000	• universal silicone spray • prevents incrustation of rubber, latex and PVC devices and also prevents them from sticking to the mucosa • CFC free • latex-free **Please note:** *SILKOSPRAY is not suitable for devices made of silicone.* *For silicone products we recommend our water-soluble lubricating gel TrachJell.*	10

TRACHJELL

REF.	DESCRIPTION	QTY
556100	• single dose water-soluble lubricating gel • 8.5 g • sterile	25

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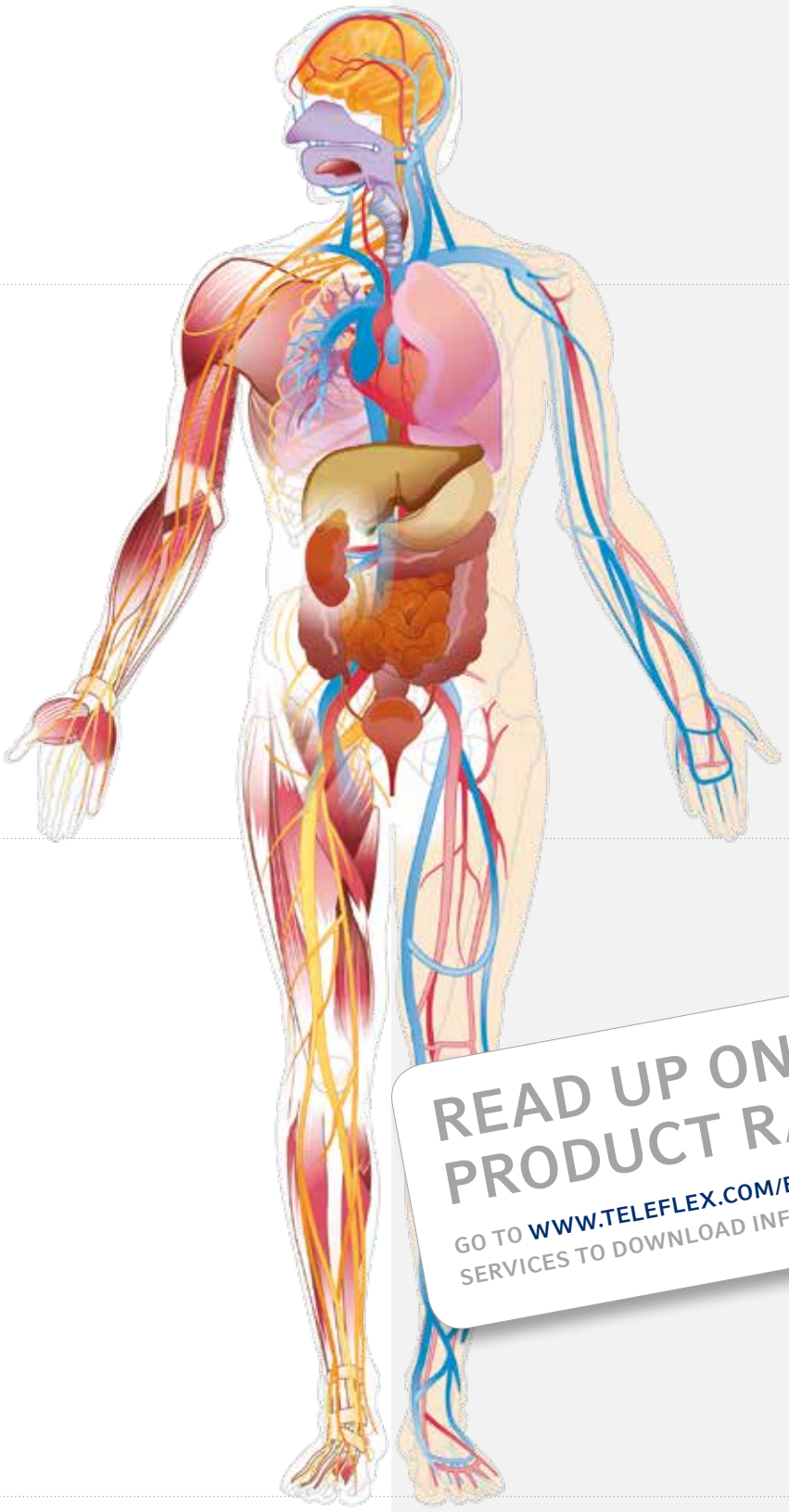

Central Venous Catheters
Haemodialysis Access
Haemodynamic Monitoring
Trauma and Surgery
Endotracheal Tubes & Double Lumen Tubes
Oropharyngeal & Nasopharyngeal Airways
Laryngoscopes
Tracheostomy
Regional Anaesthesia
Aerosol & Oxygen Therapy
Humidification
Bacterial/Viral Filtration
Surgical Instrumentation

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Central Venous Catheters
PICC
Haemodialysis Access
Haemodynamic Monitoring
Arterial Access
Trauma and Surgery
Regional Anaesthesia
Standard Bladder Management
Operative Urology and Endourology
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