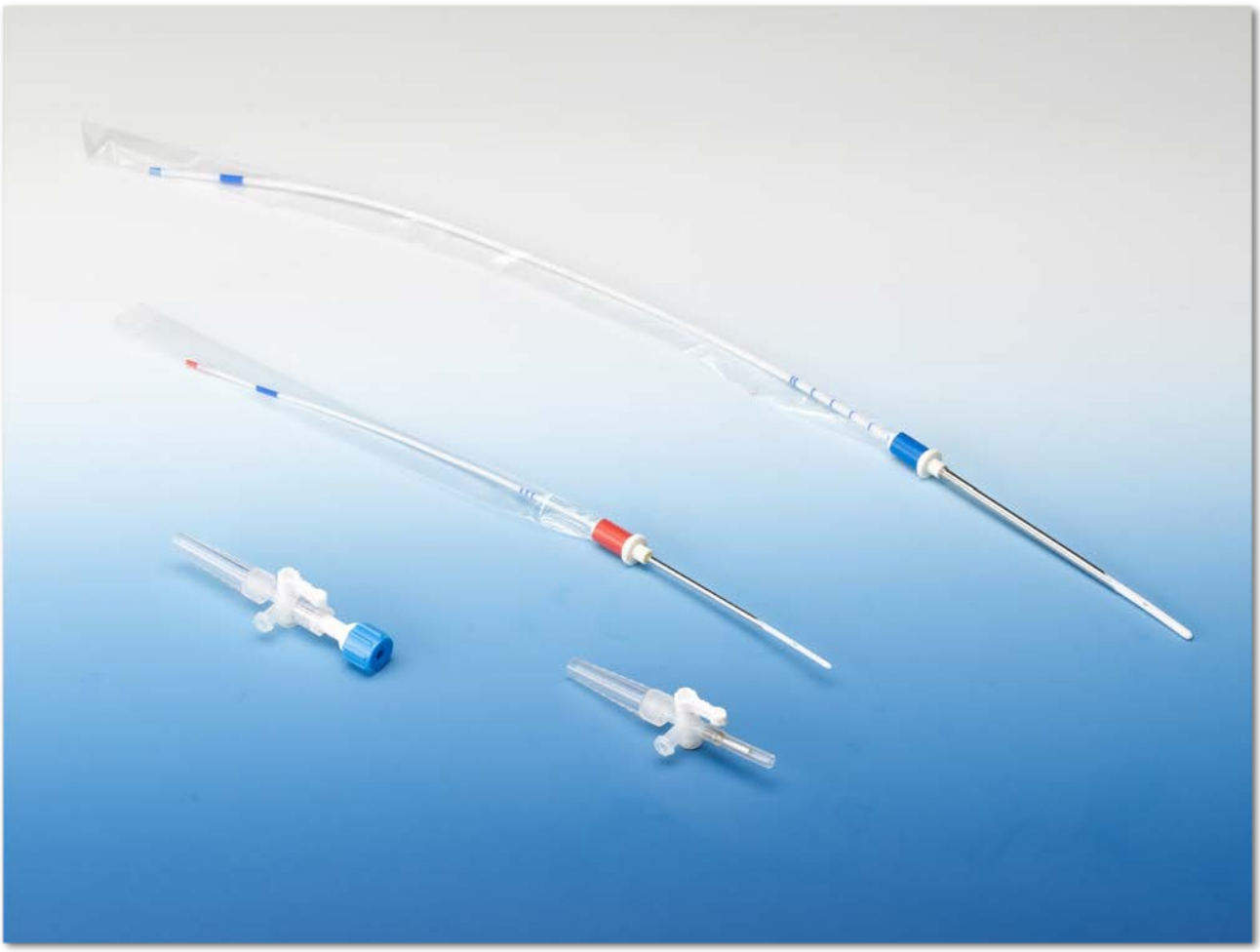
PNEUMOCATH®
NEO-PNEUMOCATH®



Digitally signed by Iarovoi Petru
Date: 2025.06.06 18:17:00 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

intra special catheters GmbH
Oststraße 2 - D-66780 Rehlingen-Siersburg
www.intra-online.de
E-Mail: info@intra-online.de Tel.: +49 / 68 35 / 92 26 - 0

Content

1. Intended Purpose

1.1 Indications and medical purpose

The PNEUMOCATH® kits are used to aspirate unwanted effusions of all kinds from the pleural cavity (pleural effusion (e.g. haematothorax, pleural empyema, chylothorax)), to remove air or gases from the pleural cavity (pneumothorax (spontaneous, traumatic, iatrogenic)) or for pleurodesis. Pleural puncture (thoracentesis) can be used for diagnostic or therapeutic purposes. The aims of the application are to initiate further therapeutic measures and, among other things, significantly to restore the physiological pressure conditions of the pleural cavity and to relieve symptoms or, in the case of pleurodesis, to obliterate the pleural leaves in order to prevent a recurrence of effusion.

1.2 Contraindications

There are no absolute contraindications, especially in case of vital (life-threatening) indication.
It is at the discretion of the attending Healthcare Professional to assess this.

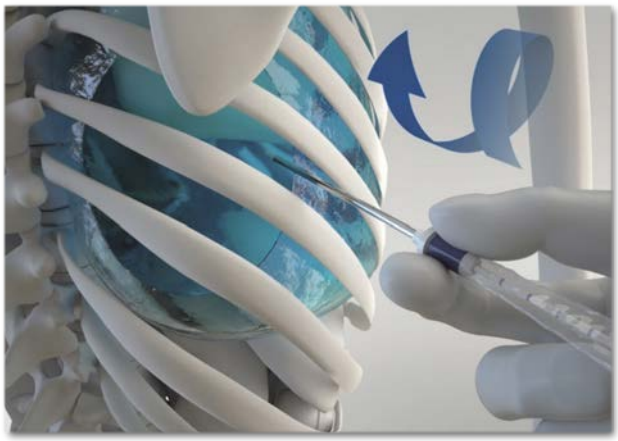
Relative contraindications:

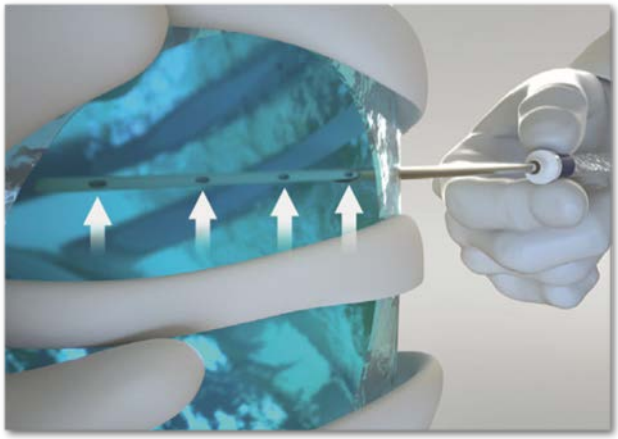
- Unwilling uncooperative patient
- Coagulopathy / haemorrhagic diathesis
- Anticoagulation
- Severe decompensation
- Infections / inflammations (e.g. infections of the pleural cavity, Florid skin infections in the area of the puncture site)
- Restricted access route to the pleural cavity (e.g. adhesions in the pleural space, malformation of the cardiac vessels, Altered anatomy of the chest wall)
- Emphysema of the lung

intra special catheters GmbH
Oststraße 2 - D-66780 Rehlingen-Siersburg
www.intra-online.de
E-Mail: info@intra-online.de Tel.: +49 / 68 35 / 92 26 - 0

1.3 Product description

The PNEUMOCATH® drainage catheters consist of a radiopaque PE tube with ring marks and side openings for suction, inserted into a puncture cannula with connected sterile sheath. At the proximal end, a three-way-stopcock with step adapter is firmly connected by means of a metal mandrel. Alternatively, a fix adapter can be used for this purpose. The catheters are inserted through the needle. Due to its small size and easy handling, the PNEUMOCATH® thoracic drainage is also suitable for paediatrics. The NEO-PNEUMOCATH® models offer higher flow rates and better suction results for drainage due to larger lumens.





1.4 Intended users and patient population

The product may only be inserted, applied and removed by Healthcare Professionals, i.e. by qualified physicians or by qualified medical personnel under the instruction of a qualified physician.

Of particular importance are the procedures in anaesthesia, intensive care, internal medicine, pneumology (pulmology), surgery and emergency medicine and for all other patients with the listed indications and where the user with the required qualifications considers this necessary.

The medical device can be used on both adults and children without any fundamental distinction as to age, anatomy or physiology, taking into account the contraindications. The anatomical and physiological conditions of the patient must be checked by the attending Healthcare Professional before using the product.

1.5 Application duration

The product is only suitable for short term (< 30 days) use.

1.6 Single use

The product is not reusable. It is a single use product.

1.7 Classification

Product group: Drains, thoracic
UMDNS: 11-308
Catheter: Class IIa (Rule 7)
Kit: Sterile procedure pack according to article 12 of the Council Directive 93/42/EEC

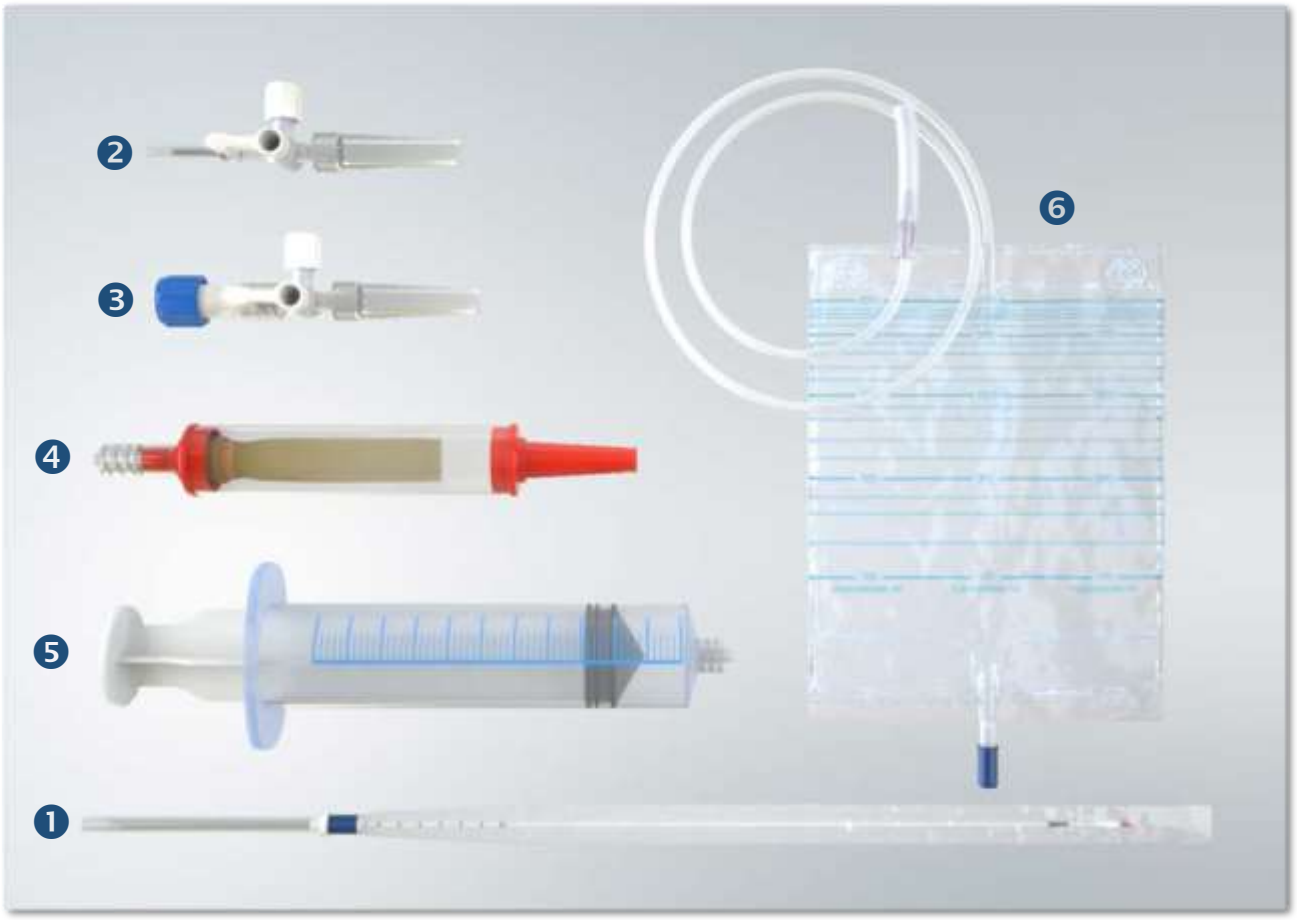
2. Packaging Content

Primary packaging content

❶ 1: Radiopaque PE-catheter with ring marks, inserted into a puncture cannula with sterile sheath and
❷ 1: Three-way-stopcock with connected step adapter (only for standard version) or
❸ 1: Fix adapter with integrated three-way-stopcock and connected step adapter (only Fix version)

Possible additional packaging contents

❹ 1: Pneumovent® (Heimlich valve)
❺ 1: Syringe 50-60 ml LL
❻ 1: Collecting bag 2.0 ltr. LL with 90cm tube
All collecting bags with back valve and bottom valve.



intra special catheters GmbH
Oststraße 2 - D-66780 Rehlingen-Siersburg
www.intra-online.de
E-Mail: info@intra-online.de Tel.: +49 / 68 35 / 92 26 - 0

3. Device and Material Specifications

Table 1: Product variants and article numbers

REF	Catheter OD / Length	Catheter ID	Needle Length	Needle OD / ID	Adapter	Collection bag and Syringe	Pneumovent®
PNEUMOCATH®							
503 001	50 cm – 8 F (2,7 mm)	1,85 mm	85 mm	3,4 x 3,1 mm	Standard		
503 002	40 cm – 8 F (2,7 mm)	1,85 mm	65 mm	3,4 x 3,1 mm	Standard		
503 003	30 cm – 6 F (2,0 mm)	1,35 mm	55 mm	2,6 x 2,2 mm	Standard		
503 201	50 cm – 8 F (2,7 mm)	1,85 mm	85 mm	3,4 x 3,1 mm	Fix		
NEO-PNEUMOCATH®							
503 011	50 cm – 10 F (3,2 mm)	2,1 mm	85 mm	4,0 x 3,5 mm	Standard		
503 012	40 cm – 10 F (3,2 mm)	2,1 mm	65 mm	4,0 x 3,5 mm	Standard		
503 014	50 cm – 10 F (3,2 mm)	2,1 mm	85 mm	4,0 x 3,5 mm	Fix		
503 211	50 cm – 10 F (3,2 mm)	2,1 mm	85 mm	4,0 x 3,5 mm	Fix		
PNEUMOCATH® - Kits							
503 401	50 cm – 8 F (2,7 mm)	1,85 mm	85 mm	3,4 x 3,1 mm	Standard + Silicone Tube Adapter	X	
503 403	30 cm – 6 F (2,0 mm)	1,35 mm	55 mm	2,6 x 2,2 mm	Standard + Silicone Tube Adapter	X	
503 501	50 cm – 8 F (2,7 mm)	1,85 mm	85 mm	3,4 x 3,1 mm	Standard + Silicone Tube Adapter	X	X
503 503	30 cm – 6 F (2,0 mm)	1,35 mm	55 mm	2,6 x 2,2 mm	Standard + Silicone Tube Adapter	X	X
503 903	30 cm – 6 F (2,0 mm)	1,35 mm	55 mm	2,6 x 2,2 mm	Standard	Set with: biliary collection bag, two surgical drapes, gauze swab, underpad, disposable gloves, gauze compress, syringe, rectangular bowl	

Table 2: Material components of the Pneumocath catheters

Product / Component	Material	Type of contact
Ⓐ Catheter tube	LDPE	Invasive (in the body, no direct contact with circulating blood). Has contact with fluids coming out of / or going into the body
Puncture needle Ⓑ(1) Canula Ⓒ(2) Grip of needle Ⓓ(3) Adhesive / Insulation tape Ⓔ(4) Protection tube	Stainless steel ABS PVC LDPE	(1) Invasive (in the body, no direct contact with circulating blood). Has contact with fluids coming out of / or going into the body
		(2) Outside the body; skin contact possible
		(3) Outside the body; skin contact possible
		(4) Outside the body; skin contact possible
Ⓕ Sterile sheath	LDPE	Outside the body; skin contact possible
Ⓖ Metal connection piece (in catheter distal) *(only Fix-Version)*	Stainless steel	Outside the body. Has contact with fluids coming out of / or going into the body
Ⓗ Distal plug	ABS	Outside the body
Three-way-stopcock *(only Standard-Version)* Ⓘ(1) Body Ⓙ(2) Adapter (LL) Ⓚ(3) Core handle Ⓛ(4) Screw cap	Nylon Nylon HDPE PP	(1)(2)(3) Outside the body; skin contact possible. Has contact with fluids coming out of / or going into the body
		(4) Outside the body; skin contact possible
Three-way-stopcock *(only Fix-Version)* Ⓜ(1) Body Ⓝ(2) Adapter (LL) Ⓞ(3) Core handle Ⓟ(4) Screw cap	PSU PSU HDPE PP	(1)(2)(3) Outside the body; skin contact possible. Has contact with fluids coming out of / or going into the body
		(4) Outside the body; skin contact possible
Ⓠ Metal kink protection tube (at Three-way-stopcock) *(only Standard-Version)*	Stainless steel	Outside the body. Has contact with fluids coming out of / or going into the body
Ⓡ Kink protection *(only Standard-Version)*	PVC / Silicon	Outside the body; skin contact possible
Tube attachment *(only Fix-Version)* Ⓢ(1) Threaded sleeve Ⓣ(2) O-Ring (Internal) Ⓤ(3) Pressure disc (Internal) Ⓥ(4) Screw cap	POM EPDM Rubber ABS ABS	(1)(2) Outside the body; skin contact possible. Has contact with fluids coming out of / or going into the body.
		(3) No direct contact
		(4) Outside the body; skin contact possible
Ⓦ Screw cap	ABS	Outside the body; skin contact possible. Has contact with fluids coming out of / or going into the body.

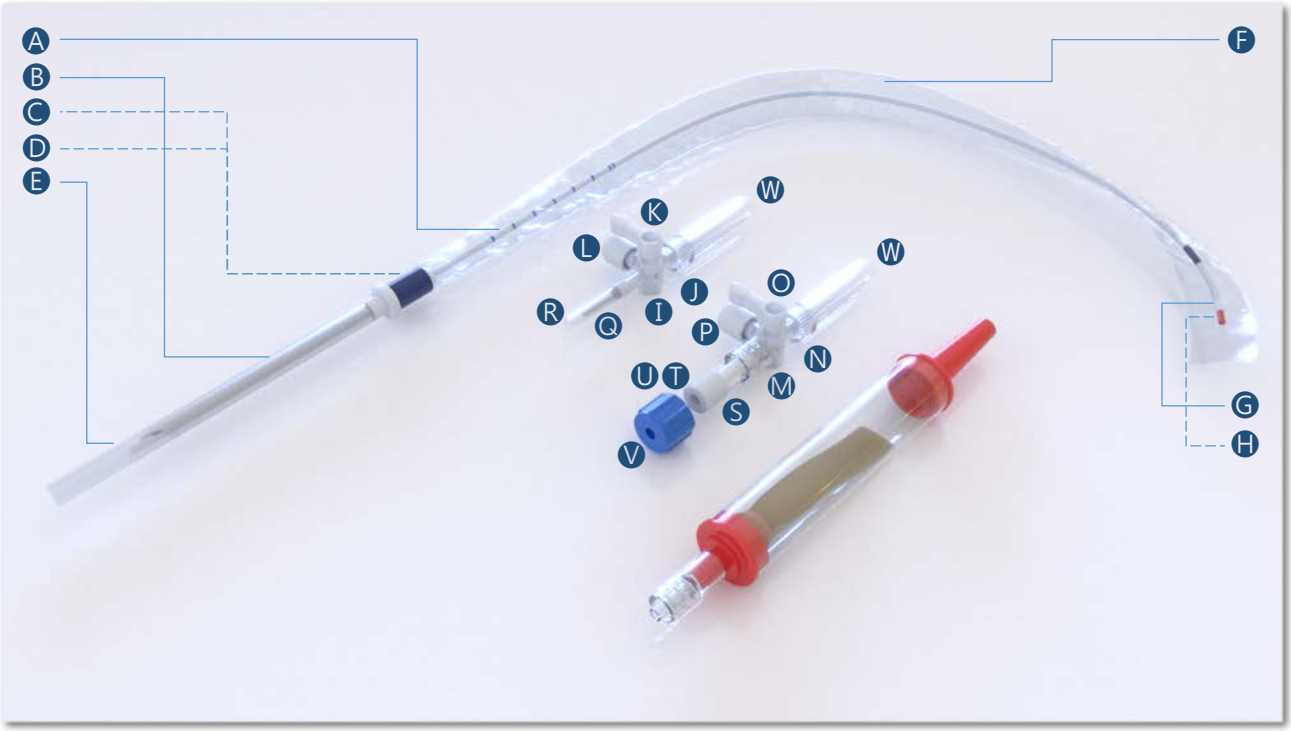


Table 3: Material components of the Pneumocath - Kits

Product / Component	Material	Type of contact
Syringe (50 - 60 ml) (1) Case (2) Plunger rod (3) Piston plug	 PP PP Polyisoprene rubber	Outside the body. Has contact with fluids coming out of / or going into the body.
Collection bag (1) Bag (2) Tube (3) Adapter (4) Bottom drain valve	 PVC PVC PVC PVC, LDPE	Outside the body; skin contact possible
Pneumovent (1) Valve chamber (2) Adapter (LL) (3) Tube adapter (4) Internal flutter valve	 PVC, DEHP ABS ABS Latex	(1)(2)(3) Outside the body; skin contact possible (4) No direct contact
Silicon tube adapter	Silicone rubber	Outside the body. Has contact with fluids coming out of / or going into the body.

4. Packaging and Sterilization

The products are packed in peel pouches, placed in cartons of 10 or 20 pieces.

The sets are sterilized with ethylene oxide according to a method validated at the physical and microbiological level. The usability period is a maximum of 5 years from the date of sterilization. Depending on the components used, a shorter shelf life may be possible, but not less than 3 years. The specific shelf life is indicated on the product label.

5. Storage and Handling Instructions

The storage and handling instructions are given on the label of the product and in the instructions for use.

6. Quality Assurance

The quality of the products is guaranteed by inspections at all levels of production.
All intra products are produced and packaged in controlled atmosphere zones.

Final inspection takes place at packaging level.

7. Regulatory Requirements

7.1 General

The Medical Device Regulation (EU) 2017/45 (MDR) has been in force since 26.05.2021 and has thus replaced the Medical Device Directive 93/42/EEC (MDD). According to Article 120 MDR, the transitional provisions apply until 26.05.2024, of which use is made for the named medical device. The implementation of the MDR is currently in progress and will take place within the mentioned period for the named medical device.

intra special catheters complies with the requirements of the MDR - (EU) Regulation 2017/745 and maintains the certificate according to the Medical Device Directive 93/42/EEC under the certification by TÜV NORD CERT GmbH (CE 0044) until 26.05.2024. intra special catheters also maintains a quality management system according to EN ISO 13485. Within the framework of the quality management system, all regulatory requirements relevant for the product group are implemented and maintained and monitored for revisions.

7.2 Implemented regulatory requirements

Medical Device Law Implementation Act (*german* MPDG)	C	DIN EN ISO 10993-1	C
Medical Devices EU Adaptation Act (*german* MPEUAnpG)	C	DIN EN ISO 10993-3	R
Medical Devices User Notification and Information Ordinance (*german* MPAMIV)	C	DIN EN ISO 10993-5	C
MDR (EU) Regulation 2017/745	C	DIN EN ISO 10993-6	R
MDD Directive 93/42/EEC	C	DIN EN ISO 10993-7	C
DIN EN ISO 13485	C	DIN EN ISO 10993-10	R
DIN EN ISO 14971	C	DIN EN ISO 10993-11	R
DIN EN ISO 20417	C	DIN EN ISO 10993-12	C*
DIN EN ISO 15223-1	C	DIN EN ISO 10993-15	R
DIN EN 868-2	C*	DIN EN ISO 10993-16	R
DIN EN 868-3	C*	DIN EN ISO 10993-17	R
DIN EN 868-4	C*	DIN EN ISO 10993-18	C
DIN EN 868-5	C*	DIN EN ISO 80369-7	C
DIN EN ISO 11607-1	C*	DIN EN ISO 20697	C
DIN EN ISO 11607-2	C*	DIN EN ISO 14644-1	C*
DIN EN 556-1	C*	DIN ISO 2859-1	R
DIN EN ISO 11737-1	C*	DIN EN 62366-1	R
DIN EN ISO 11737-2	C*	ASTM International F2503-20	R
DIN EN ISO 11135	C*	ISO/TR 20416	R

Overview of abbreviations

"C" (Compliance)	*Regulatory requirements that are mandatory*
"R" (Reference)	*Regulatory requirements that are not mandatory but serve as a reference*
*„ * “*	*Regulatory requirements that are applied by subcontractors within the scope of the service to be provided*

intra special catheters GmbH
Oststraße 2 - D-66780 Rehlingen-Siersburg
www.intra-online.de
E-Mail: info@intra-online.de Tel.: +49 / 68 35 / 92 26 - 0