

EC Certificate - Production Quality Assurance

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

No.**CE 01966****Issued To:****Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden**

In respect of:

See certificate scope page.

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-06-29**Date: **2018-05-30**Expiry Date: **2023-06-28**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W9 4AL, UK.
A member of BSI Group of Companies.



We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

Sterilisation after assembly:	<i>EtO, Ethylene Oxide</i>
CE certificate	<i>CE 01966</i>
Certificate issued by	<i>BSI (0086)</i>

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

[Signature]
Name of signing person

RA Manager, Medical Devices



Title: Mölnlycke Procedure Trays MDD Article 12 (former Class IIa trays)

Page 2(2)

Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care**Authorised Signatory:**
Name of signing person

RA Manager, Medical Devices



Göteborg 2006-08-07

To Whom It may concern:

We hereby declare that,

Following Mölnlycke Health Care surgical drapes comply with the High Performance requirements of EN13795:

- Klinidrape® laminated Patient Drapes
- BARRIER® reinforced and laminated Patient Drapes
- Klinidrape® and BARRIER® Stockinettes and plastic/laminated Leggings
- Klinidrape® and BARRIER® Table Covers and Mayo Stand Covers

Following Mölnlycke Health Care surgical drapes comply with the Standard Performance requirements of EN13795:

- Klinidrape® Utility Drapes
- BARRIER® non-reinforced Patient Drapes (less critical area)
- Klinidrape® and BARRIER® nonwoven OP-tapes (less critical area)
- Klinidrape® and BARRIER® fluid repellent Leggings and Supplementary Products (less critical area)

Mölnlycke Health Care standard Klinidrape® and BARRIER® Surgical Gowns comply with the Standard Performance requirements of EN13795.

Mölnlycke Health Care reinforced Klinidrape® and BARRIER® Surgical Gowns comply with the High Performance requirements of EN13795

Mölnlycke Health Care Clean Air Suits comply with the performance requirements of EN13795



Anders Odmyr
International Technical Support Manager
Drapes and Sets





Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

This is to certify that:

**Mölnlycke Health Care AB
Gamlestadvägen 3 C
S-402 52
Göteborg
Sweden**

Holds Certificate No: **FM 39247**

and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

For and on behalf of BSI:

Managing Director, BSI Management Systems (CEMEA)

Originally registered: **31/03/1998**

Latest Issue: **10/01/2007**



Page: 1 of 3

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The British Standards Institution is incorporated by Royal Charter.
Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom



BSI
Management
Systems

Certificate No: **FM 39247**

Location

Registered Activities

Mölnlycke Health Care AB
Gamlestadsvägen 3 C
S-402 52 Göteborg
Sweden

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

Mölnlycke Health Care Oy
PO Box 76
Saimaankatu 6
Mikkeli
FIN 50101
Finland

Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs.

Mölnlycke Health Care AB
Mölnlycke Health Care (Thailand) Lt
160 Bangplee Industrial Estate
Bangna-Trad Rd
Samutprakarn
Bansaothong
10540
Thailand

Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.

Mölnlycke Health Care AB
T/A Mölnlycke Health Care SA
Parc Industrial
B-4300 Waremmé
Belgium

Manufacture of sterile drapes, operating sets and procedure packs.

Mölnlycke Health Care Klinipro s.r.
Na Novem Poli 382
Prumysiova zona Karvina
Karvina - State Mesto
733 01
Czech Republic

Manufacture of surgical drapes and procedure packs.

Originally registered: **31/03/1998**

Latest Issue: **10/01/2007**

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Certificate No: **FM 39247**

Location

Registered Activities

Mölnlycke Health Care AB
Mölnlycke Health Care (Thailand) Lt
Amata Nakorn (Bang Pakong)
Industrial Estate
700/461 Moo Bangha-Trad Rd. KM.57
Tambol Donhuaroh, Amphur Muang
Chonburi 20000
Thailand

Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.

Mölnlycke Health Care AB
Tubiton House
Medlock Street
Oldham
OL1 3HS
United Kingdom

The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products.

Mölnlycke Health Care AB
Lot 9, Lorong Perusahaan 4
Kulim Industrial Estate
PO Box 52, 09000 Kulim
Kedah Darulaman
Malaysia

The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Mölnlycke Health Care AB
Plot 204 Kawasan Perindustrian
Kula Ketil
Phas II
09300 Kula Ketil
Malaysia

The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Mölnlycke Health Care AB
Lot B5 & B6
Kawasan Perindustrian Miel
Batang Kali Phase II
44300 Batang Kali
Malaysia

The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

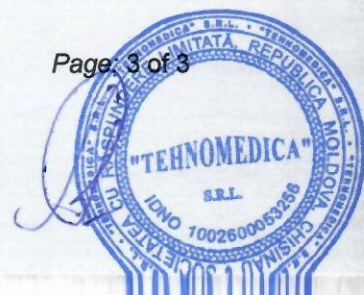
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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number:

MD 83345

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

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.

The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21

Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28

Expiry Date: 2021-11-27

Page: 1 of 2



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A Member of the BSI Group of Companies.



Certificate No: **MD 83345**

Location

Registered Activities

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

Mölnlycke Health Care Pty Ltd
Level 4
12 Narabang Way
Belrose
New South Wales
2085
Australia

The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments.

Original Registration Date: 2004-07-21

Latest Revision Date: 2018-11-26

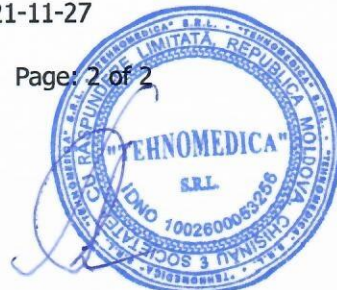
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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713168177

Valid from:

2020-05-06

Valid until:

2024-05-26

Date,

2020-05-14

Christoph Dicks
Head of Certification/Notified Body



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00



Certificate

No. Q5 012974 0606 Rev. 00

Holder of Certificate: **B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA guide wires and sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial puncture cannula, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713160067

Valid from: 2019-10-08

Valid until: 2022-09-30

Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

Certificate

No. Q5 012974 0606 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

./.

Číslo setu: 97038757-02
Revize návodky: 34
Status: REL TO PRODTN
Datum revize: 17.07.2018
Platnost BOMu: 01.08.2018 do 31.12.9999



97038757 Set Radial Angio absorbant steril


Komponent	Číslo komponentu	Ks/set
Crepe paper 60x60cm 45g/m2 White	2316730-00	1
BNS Radial Angiography Drape 240x330cm 5	958284-07	1
NS. Kidney bowl 800ml Polypropylene Yell	2308944-00	1
BNS Adhesive towel 50x50cm	947064-07	1
NS.bowl gallipot 250ml PP pink graduated	2308024-00	1
BNS Absorbent Towel 34x50cm	830204-07	1
Gallipot 120ml Graduated Clear Plastic	2302055-00	1
Bowl 2500ml Polypropylene Blue Guidewire	2314188-00	1
Medicine/Specimen cup 100ml Polypropylen	2315740-00	1
Forceps Tube Clamp Plastic Green 10cm	2300323-00	1
FORCEPS GREEN DISPOSABLE	2302144-00	1
Banded Bag Circular 75cm	15351-90	1
BNS Banded Bag 140cm	990375-10	2
BNS Surgical Gown PR SP XL	68000624-02	2
Hand towel white 47x38 cm White	2308641-00	4
Table Cover 150x190 Abs. 75x190cm Wrappi	5200460-08	1
Breather Bag 613x504mm	32635-92	1
Insert Card for Mölnlycke Procedure Tray	40777-92	1
SA Label 1,6 x 5cm TEHNOMEDICA SRL	2322733-00	1

Metoda balení: A
Ks do krabice: 3
Země určení: Moldavia

POZNÁMKA - set:


Text na S/B etiketě:

CATALOGUE PAGES

Name:	Set steril pentru Angiografie	 B BRAUN B. Braun Meisungen AG - Vascular Systems -
Drawing number:	L000032264C1	
Article number:	5010783	
Customer ID:		Sales rep.: Ms. Birgit Körber
Customer:		Country: Moldova
Status of the kit:	active	


Single kit components			
Amount	Name	Article no.	Notes
1	Angiographic syringe 12 ml	8914798	
1	Puncture Needle 1,3 x 70 mm, 18G	8415692	
1	Scalpel Cutfix fig. 11	8508216	
1	Guidewire J3FC-FS175-035	8919755	
30	Compress gauze 10 x 10 cm, 12-ply	8913014	
2	Sterican Cannula 0,80 x 40 mm, 21G	16010450	
1	Sterican Cannula 0,70 x 30 mm, 22G	16010400	
1	Syringe Omnifix 2 ml, Luer Lock, transparent	8508461	
1	Syringe Omnifix 5 ml, Luer Lock, transparent	8508607	
1	Syringe Omnifix 10 ml, Luer Lock, transparent	8508429	
1	Syringe Omnifix 20 ml, Luer Lock, transparent	8508470	
1	Guidewire bowl 2500 ml, blue	8915530	
1	Cover drape 100 x 150 cm	8911561	en: wrapping drape pl: do zawinięcia zestawu

CATALOGUE PAGES

Name:	Set steril pentru Angiografie	 B. Braun Meisungen AG - Vascular Systems -
Drawing number:	L000032264C1	
Article number:	5010783	
Customer ID:		Sales rep.: Ms. Birgit Körber
Customer:		Country: Moldova
Status of the kit:	active	

Subassembly: Additional information for production			
Amount	Name	Article no.	Notes
Baugruppe: Additional information for production 1 x Rampă 3 căi OFF, integrată cu s-m contrast, perfuzie, tub 1 x Seringă angiografică 12 ml, cu rotator 1 x Ac puncție 18G, 7 cm, roz 1 x Bisturiu Cutfix E11 1 x Ghid conductor 175 cm, J3, 0.035" 30 x Tampon de tifon 10 x 10 cm 12-straturi 2 x Ac Sterican G21 1/2, 0,8 x 40 mm, verde 1 x Ac Sterican G22 0,7 x 30 mm, negru 1 x Seringă Omnifix LL, 2ml 1 x Seringă Omnifix LL, 5ml 1 x Seringă Omnifix LL, 10ml 1 x Seringă Omnifix LL, 20ml 1 x Bol 1 x Cearșaf steril 100 x 150 cm			

CATALOGUE PAGES

Name:	Set steril pentru Angiografie	 B BRAUN B. Braun Meisungen AG - Vascular Systems -
Drawing number:	L000032264C1	
Article number:	5010783	
Customer ID:		Sales rep.: Ms. Birgit Körber
Customer:		Country: Moldova
Status of the kit:	active	

Subassembly:		Manifold	
Amount	Name	Article no.	Notes
1	Combidyn tubing 150 cm, red	8910186	
1	Rotator m/m	8910160	
1	Manifold 3-fold, OFF, 35 bar	8910022	
2	Tape for fixation "Japan"	8919600	
1	Contrast Media System 180 cm	8914410	
1	Infusionsystem ventilated 190 cm	8914561	

CATALOGUE PAGES

Name:	Set steril pentru Angiografie	B BRAUN
Drawing number:	L000032264C1	B. Braun Meisungen AG
Article number:	5010783	- Vascular Systems -
Customer ID:		Sales rep.: Ms. Birgit Körber
Customer:		Country: Moldova
Status of the kit:	active	

Packaging material		Kits per box: 10	
Amount	Name	Article no.	Notes
1.01	Medipeel bag 42 x 38 cm	8917777	
1.05	Pro-Set small	12156086	
1.03	Label 167 x 235, blank	8910998	en: Mit rumänischer Komponentenliste pl: etykietę w j.rumuńskim umieścić na zawiniętym zestawie, w dobrze widocznym z zewnątrz miejscu, następnie zgrzać worek
0.1	Box 570 x 370 x 310 mm	6605010	pl: 10 szt / karton 6605010
0.13	Label 148 x 124 mm, blank	8911108	
0.2	Adhesive tape 1000 m x 75 mm	8954280	
0.1	PE-bag 75 x 55 x 100 cm	8413100	de: www-Version lt, Mail B. Körber v. 24.6.19 / Hdt

Latex ● Biogel® Surgeons



The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.



ACTUAL COLOUR REF 822

Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort¹
- Reduced chance of a hole with an industry-leading AQL* result of 0.65¹
- Every glove (100%) is air inflation tested and visually inspected for quality and safety¹
- Improved efficiency as less gloves are wasted²
- Non-pyrogenic, potentially reducing the risk of post-operative complications³

Recommended use

Recommended for all surgical procedures.

Material information

- Natural rubber latex
- Micro-roughened surface
- Biogel hydrogel polymer coating
- Beaded cuff
- Powder-free
- Non-pyrogenic

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. The industry standard requirement for AQL* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves².

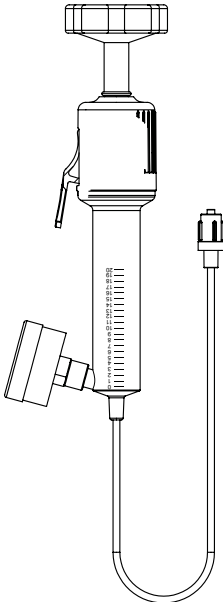
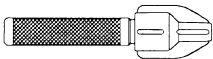
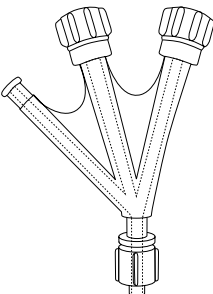
Re-order REF 822

REF	Size	Pairs
82255	5 ½	50/Box
82260	6	50/Box
82265	6 ½	50/Box
82270	7	50/Box
82275	7 ½	50/Box
82280	8	50/Box
82285	8 ½	50/Box
82290	9	40/Box

4 boxes per case

Accessories for PTCA

INFLATION DEVICES, Y-CONNECTOR, KISSING BIBALLOON ADAPTER

	Inflation Device for PTCA	Code- Number	Sales unit-pcs.
	Pressure gauge: <ul style="list-style-type: none"> - 90° rotating manometer for „custom“ handling - coded figures from nominal to burst pressures for easy reading Body and button: <ul style="list-style-type: none"> - advanced mechanism for rapid pressure increase, i.e. effective and fast procedure - grip design for better handling - clear material for easy air bubble detection and removal Handle: <ul style="list-style-type: none"> - ergonomic design for optimal handling - progressive resistance while inflating for pressure feedback 		
	Inflation Device for PTCA, 20 ml/30 atm	5028901	1
	Torquer Torque device for guide wires <ul style="list-style-type: none"> - luminescent - wire grip for all diameters up to 0.022" 		
	Torque device	5023687	10
	Y-Connector For all interventional techniques <ul style="list-style-type: none"> - with rotational adaptor and Touhy-Borst-valve - 9.5F lumen 		
	Y-connector with plastic insertion tool	5021693	10
	Double Y-connector with plastic insertion tool	5020743	5
	Unique Kissing BiBalloon adaptor For simultaneous and/or sequential dilatation of bifurcation lesions <ul style="list-style-type: none"> - innovative approach for multiple dilatation techniques - final kissing balloon inflation 		
	Kissing BiBalloon adaptor	5014760	25