Intravenous Administration Set Accessories – Protective Caps for Connectors
Sterile, for single use

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O

TDS number: QS-TDS028 – Rev. 01
2020-October

1. General Information

1.1 Intended use

The protective caps are intended to close off open ports of intravascular devices such as infusion sets.

1.2 General description

The protective caps can be used for both male and female luer locks.

The following materials: PVC, PHT, DEHP, natural rubber latex are not part of the material formulation.



BD Catalog Number	BD Product Description	Tube Length (cm)	Total Set Length (cm)	Priming Volume (ml)	Tube Inner Diameter (cm)	Tube Inner Diameter (cm)
TP	Luer Lock Cap	N/A	N/A	N/A	N/A	N/A
TP-MF	Male-Female Luer Lock Cap, red	N/A	N/A	N/A	N/A	N/A
TP-MF-B	Male-Female Luer Lock Cap, white	N/A	N/A	N/A	N/A	N/A
TP-MF-C	Male-Female Luer Lock Cap, blue	N/A	N/A	N/A	N/A	N/A
TP-MF-O	Male-Female Luer Lock Cap, orange	N/A	N/A	N/A	N/A	N/A

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to use the BD Catalog Number.

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Further features:

BD Catalog Number	Gravity Use	Pump Use	Ventilation Spike	Back Check Valve	Filter Size	Change Interval	Lipid Resistant
TP	Yes	No	N/A	N/A	N/A	According to hospital protocol	Yes
TP-MF	Yes	No	N/A	N/A	N/A		Yes
TP-MF-B	Yes	No	N/A	N/A	N/A		Yes
TP-MF-C	Yes	No	N/A	N/A	N/A		Yes
TP-MF-O	Yes	No	N/A	N/A	N/A		Yes

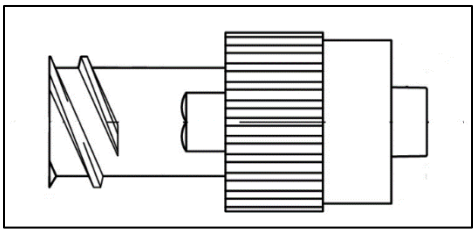
Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
TP TP-MF TP-MF-B TP-MF-C TP-MF-O	**Address:** Zibo Qiaosend Medical Articles Co., Ltd No.2, Gaoyuan East Road, 256300 Gaoqing County, Shandong Province, People's Republic of China **ISO 13485** Certificate No.: Q5 088861 0011	CE certified with TÜV SÜD Certificate No.: G2S 088861 0010	**Address:** Zibo Qiaosend Medical Articles Co., Ltd No.2, Gaoyuan East Road, 256300 Gaoqing County, Shandong Province, People's Republic of China **ISO 13485** Certificate No.: Q5 088861 0011	MedNet EC-REP GmbH Borkstraße 10 48163 Münster Germany Tel : +49 (0) 251 322 66 64

1.3 Materials

Component	Material
TP	Polyethylene (PE)
TP-MF	Polypropylene (PP)
TP-MF-B	Polypropylene (PP)
TP-MF-C	Polypropylene (PP)
TP-MF-O	Polypropylene (PP)

Example product drawing (TP-MF)



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1.4 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
Phthalates	Phthalates including DEHP are not part of the material formulation
Latex	Natural rubber latex is not part of the material formulation or packaging
Bisphenol A	Bisphenol A is not part of the material formulation
Substances of animal origin BSE/TSE	The products were assessed for TSE (Transmissible Spongiform Encephalopathy) contamination risk. The raw materials used in the manufacture of this device do not contain any animal tissue but may contain very small amounts of animal derived raw materials. This product is manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow derived materials have been produced using multiple cycles of conditions at least as rigorous (and normally more rigorous) as those specified in Annex C.5 of EN ISO 22442-1. Therefore, the raw materials meet or exceed the requirements of EN ISO 22442-1. The raw materials do not to present any risk with respect to TSE or other animal borne diseases.
Polyvinyl chloride (PVC)	Polyvinyl chloride is not part of the material formulation
PET/PETG	PET/PETG are not part of the material formulation

1.5 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging of the Zibo Qiaosend Protective Caps for Connectors, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 27 June 2018 according to Art. 59 (1.10) of the Regulation (EC) N° 1907/2006 (REACH).

1.6 Biocompatibility

Zibo Qiaosend Medical Articles Co., Ltd products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.7 Sterilization method

These products are sterilized using Ethylene Oxide according to ISO 11135:2014 (Sterilization for Healthcare products- Ethylene Oxide: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices). ETO residues are within applicable regulations.

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1.8 Shelf life and storage conditions

The Protective Caps for Connectors shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time. They have a shelf life of 48 months.

Store in a dry and warm place, not exposed to strong light. Avoid extreme conditions of humidity and temperature.

1.9 Standards

As per extract from the Declaration of Conformity QSZC03-03E-001-11 linked to CE certificate number G2S 088861 0010:

Harmonized Standards	
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008 / AC 2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
Non-Harmonized Standards	
EN ISO 8536-4:2020	Infusion equipment for medical use. Infusion sets for single use, gravity feed
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 11135:2014	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.10 Classification

Class Is Medical Device under **Rule 2,** Annex IX of Medical Devices Directive 93/42/EEC as amended.

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1.11 GMDN and UMDNS code

The protective caps are referenced as follows:

GMDN Code: 58977
GMDN Term: Basic Intravenous Administration Set

UMDNS Code: 12157
UMDNS Term: Intravenous Administration Sets

1.12 Manufacturing practices

Zibo Qiaosend Medical Articles Co., Ltd. is following the *Medical Equipment Production & Quality Management Standard* issued by the NMPA (equivalent to GMP)

The entire manufacturing and testing processes follow the Good Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- Zibo Qiaosend operates a system of internal and external audits to maintain compliance.
- Zibo Qiaosend confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.13 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact *(Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs")* is not required as Zibo Qiaosend products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

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2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
TP	Luer Lock Cap	1	100	1000	No
TP-MF	Male-Female Luer Lock Cap, red	1	100	1000	No
TP-MF-B	Male-Female Luer Lock Cap, white	1	100	1000	No
TP-MF-C	Male-Female Luer Lock Cap, blue	1	100	1000	No
TP-MF-O	Male-Female Luer Lock Cap, orange	1	100	1000	No

*"No": IFU may be available but not as an insert.

2.2 Packaging material

Component	Material
Unit Pack	Medical grade paper 60g + PE film
Shelf Box	Carton
Shipping Case	Carton
IFU	N/A

2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Languages: English, Bulgarian, Czech, Danish, German, Greek, Spanish, Estonian, Finnish, French, Croatian, Hungarian, Italian, Lithuanian, Latvian, Dutch, Norwegian, Polish, Portuguese, Romanian, Russian, Slovak, Slovenian, Serbian, Swedish, Turkish, Japanese, Chinese

Example primary packaging label (TP-MF)

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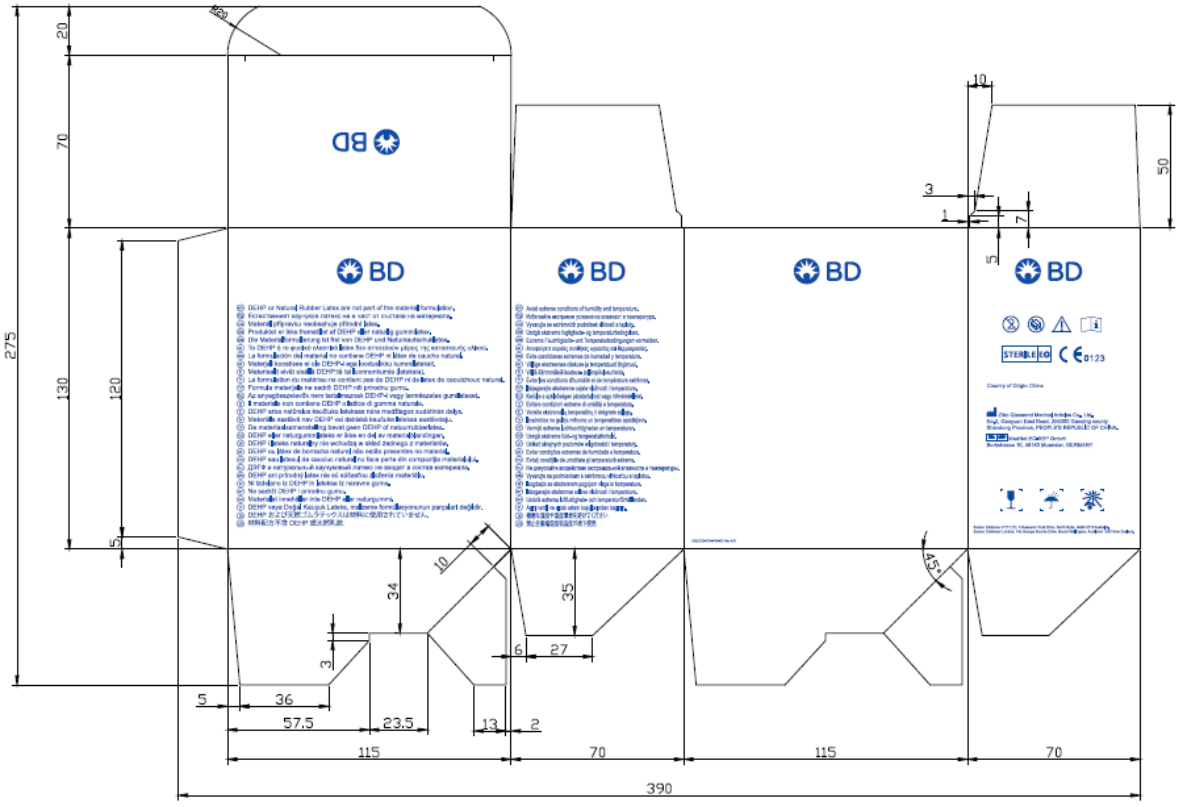
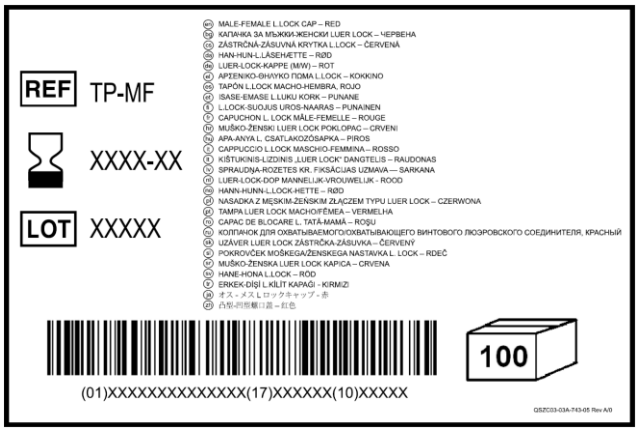
Example shelf box (TP-MF)



Example shelf box label (TP-MF)



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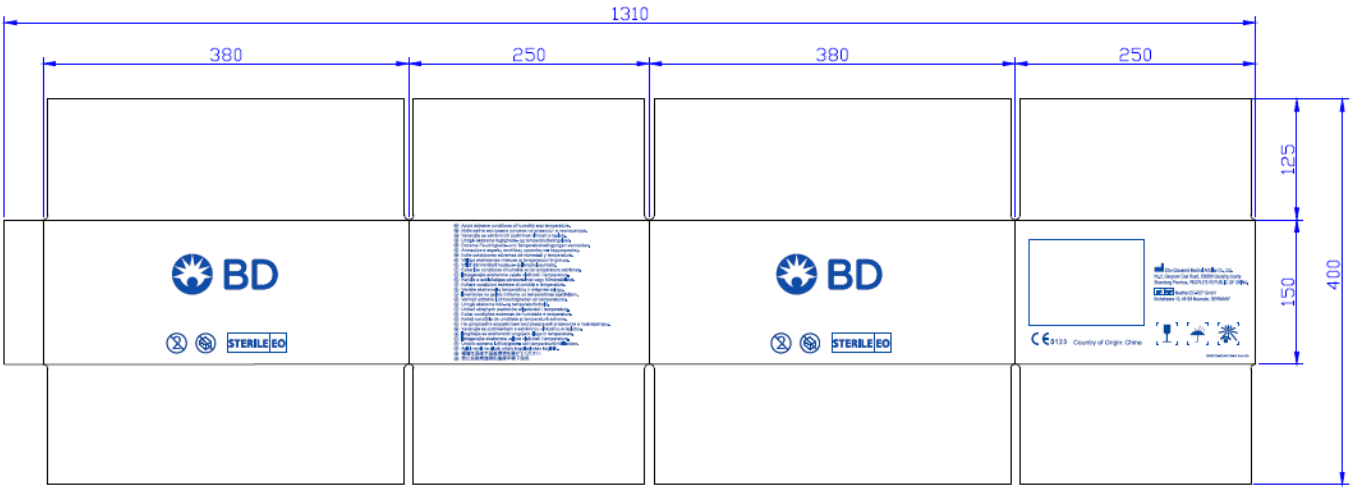
Example shipping case (TP-MF)



Example shipping case label (TP-MF)

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REVISION	CHANGE SUMMARY
01	Initial release according to new template

Third Party Approval

REVISION	CHANGE SUMMARY	DATE	SIGNATURE	COMPANY STAMP
01	Initial release according to new template	Oct. 29 2020		ZIBO QIAOSEND MEDICAL ARTICLES CO.,LTD 淄博舒森医疗用品股份有限公司 GENERAL MANAGER

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