Document Number: EMEA-SOP039-F1	Rev. Lev.: 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

Male / Female Luer Lock
Sterile
Product codes: TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O

Zibo Qiaosend Medical Articles Co., Ltd.
No.88, Tianheng Road, Gaoqing County, 256300 Zibo, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Plug Luer Male / Female
Sterile and Non-Sterile
Product codes: TP-P-B, TP-P-Y

TDS number: V201-119 Rev. 02
Veeva Vault number: BD-148006
2025-April

1. General Information

1.1 Intended purpose

Plug Luer Male / Female (TP-P-B, TP-P-Y): The Combi Plugs are the common Luer caps for both Male Luer and Female Luer. There are Sterile Combi Plugs and Non-sterile combi Plugs.

Male / Female Luer Lock (TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O): Intended to be used in connection with infusion and injection apparatus.

1.2 Intended User

The Male / Female Luer Lock and the Plug Luer Male / Female are intended to be used by healthcare professionals.

1.3 General Medical Devices description

- **Plug Luer Male / Female** (TP-P-B, TP-P-Y)*:*
  Combi Plugs are the Luer caps for both Male Luer and Female Luer. There are Sterile Combi Plugs with blister packaging and non-sterile combi Plugs with bulk packaging.

- **Male / Female Luer Lock** (TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O):
  Female Luer Lock cap (TP) is for Female Luer Lock;
  Male/Female Luer Lock caps (TP-MF, TP-MF-B, TP-MF-C, TP-MF-O) are for both Male Luer Lock and Female Luer Lock.
  The above caps are intended to be used to provide airtight protection for connectors by the physical barrier of Luer connection, and prevent medical devices from being contaminated and unintended touching.

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.



Figure 1: TP



Figure 2: TP-MF

Figure 3: TP-MF-B



Figure 4: TP-MF-C



Figure 5: TP-MF-O



Figure 6: TP-P-Y and TP-P-B

BD Catalogue Number	BD Product Description	Colour Code
TP	Male Luer Lock Cap	White
TP-MF	Male-Female Luer Lock Cap	Red
TP-MF-B	Male-Female Luer Lock Cap (White)	White
TP-MF-C	Male-Female Luer Lock Cap (Blue)	Blue
TP-MF-O	Male-Female Luer Lock Cap (Orange)	Orange
TP-P-B	Plug Luer Male / Luer Female (Non-Sterile Bulk)	Yellow
TP-P-Y	Plug Luer Male / Luer Female (Sterile)	Yellow

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

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

1.4 Certification

BD Catalogue Number	Legal Manufacturer and ISO 13485 Certification	CE/UKCA Certificate Number and Notified Body Acronym and Number	Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative/ CH Representative/ UK Representative (if applicable)
TP TP-MF TP-MF-B TP-MF-C TP-MF-O TP-P-Y	Name and Address: Zibo Qiaosend Medical Articles Co., Ltd. No.88, Tianheng Road, Gaoqing County, 256300 Zibo, Shandong Province, PEOPLE'S REPUBLIC OF CHINA ISO 13485 Certificate No.: Q5 114010 0001	CE certified with TÜV SÜD (0123) MDD Certificate No.: G2S 088861 0010 UKCA certified: N/A	Name and Address: Zibo Qiaosend Medical Articles Co., Ltd. No.88, Tianheng Road, Gaoqing County, 256300 Zibo, Shandong Province, PEOPLE'S REPUBLIC OF CHINA ISO 13485 Certificate No.: Q5 114010 0001	Name and Address: EC Representative: MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany Name and Address: CH Representative: MedNet SWISS GmbH D4 Platz 4, 6039 Root D4, Switzerland. Name and Address: UK Representative: MediMap Ltd. 2 The Drift, Thurston, Bury St Edmunds, Suffolk, IP31 3RT United Kingdom
TP-P-B		CE certified: N/A UKCA certified: N/A		

1.5 UDI-DI and Basic UDI-DI

BD Catalogue Number	UDI-DI	Basic UDI-DI
TP	Inner box: 08428820018043 Outer case: 08428820005944	697253648602LY
TP-MF	Inner box: 06972536480332 Outer case: 06972536480349	697253648602LY
TP-MF-B	Inner box: 06972536480356 Outer case: 06972536480363	697253648602LY
TP-MF-C	Inner box: 06972536480301 Outer case: 06972536480417	697253648602LY
TP-MF-O	Inner box: 06972536480288 Outer case: 06972536480295	697253648602LY
TP-P-Y	Inner box: 06972536480523 Outer case: 06972536480530	697253648602LY
TP-P-B	Inner bag: 06972536480547 Outer case: 06972536480554	697253648604M4

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

1.6 Materials

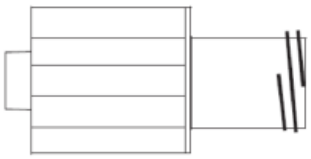


Figure 7: Example of product configuration, product reference TP-MF

BD Catalogue Number	Component	Material
TP	Cap	Polyethylene (PE)
TP-MF	Cap	Polypropylene (PP)
TP-MF-B	Cap	Polypropylene (PP)
TP-MF-C	Cap	Polypropylene (PP)
TP-MF-O	Cap	Polypropylene (PP)
TP-P-Y	Plug	Polypropylene (PP)
TP-P-B	Plug	Polypropylene (PP)

1.7 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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 February 2025, manufacturer has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzendicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS# 68648-93-1), Benzyl butyl phthalate (BBP) (CAS# 85-68-7), Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), Dibutyl phthalate (DBP) (CAS# 84-74-2), Diisobutyl phthalate (DIBP) (CAS# 84-69-5), Diisopentyl phthalate (DIPP) (CAS# 605-50-5), Dipentyl phthalate (DPP) (CAS# 131-18-0), N-pentyl-isopentyl phthalate (CAS# 776297-69-9), or Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% w/w.

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Material	Comment
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 February 2025, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A (BPA)	Manufacturer has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the articles with the product numbers referenced above. It is not a building block of any of the raw materials utilized and is not intentionally added. Manufacturer has not done any testing to evaluate levels of this chemical in these products.
Animal Derivatives	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acid and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2020 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, and EU No 722/2012).
Polyvinyl Chloride (PVC)	The medical devices referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC.
RoHS directive, heavy metals, brominated flame retardants, and phthalates	It is Manufacturer's view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive. Based on our ongoing data collection efforts and/or information received from our suppliers as of 20 February 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products. Furthermore, based on our ongoing data collection efforts and/or information received from our suppliers as of 20 February 2025, Manufacturer has not identified any bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) in an individual concentration above 0.1% w/w in the above-listed products.
Class 1A and 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) & Endocrine-Disrupting (ED) Substances	Manufacturer has been collecting data on Class 1A and Class 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) & Endocrine-disrupting (ED) chemicals to meet Medical Device Regulations (MDR) 2017/745 and 2017/746. Based on the information received from our suppliers as per 20 February 2025, we have not been made aware of any Class 1A or Class 1B CMR, or ED substances in the components that are invasive, (re)administer medicines, body liquids or other substances, including gases, to/from the body at concentrations greater than 0.1% w/w. This includes ED substances covered by Article 5(3) of Regulation EU 528/2012. Please note that the data collection process is continuing.
Heavy Metals in Packaging, according to TPCH/CONEG and EU 94/62/EC (2004)	Based on our ongoing data collection efforts and/or information received by our suppliers as per 20 February 2025, the products (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 February 2025, Zibo Qiaosend Medical Articles Co., Ltd has not identified any chemicals in the articles and packaging with the product numbers as referenced above, 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 2024 according to Art. 59 (1,10) of the Regulation (EC) No. 1907/2006 (REACH).

1.9 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.

1.10 Sterilisation method

Products are sterilized using Ethylene Oxide according to EN ISO 11135: 2014/A1 2019.

1.11 Shelf life and storage conditions

The Male / Female Luer Lock and the Plug Luer Male / Female shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

The Male / Female Luer Lock and the Plug Luer Male / Female have a shelf life of **48 months.**

- For the Plug Luer Male / Female (Sterile and Non-Sterile: TP-P-B, TP-P-Y): Processing by the user, such as sterilisation, might impact the shelf life of the products.

Zibo Qiaosend Medical Articles Co., Ltd recommend to store in a dry and warm place, not exposed to strong light nor extreme temperature.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 13485:2016 /A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes	Full
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices	Full
EN ISO 8536-4:2020	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Full

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide.	Full
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitisation	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices -Part 23: Test for irritation	Full
EN ISO 15223-1:2021	Symbols to be used with medical device labels, labelling, and information to be supplied	Full
EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes	Full
EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide	Full
ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	Full
ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	Full
ASTM F 1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Full

Note:
The above standards reflect the status at time of document release.

1.13 Classification

The **Male / Female Luer Lock (TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O)** are classified as **Class Is** as per Rule 2 of Annex IX (Medical Devices Directive 93/42/EEC).
The **Plug Luer Male / Female (TP-P-B)** is classified as **Class I non-sterile** as per Rule 1 of Annex VIII (Medical Device Regulation 2017/745).
The **Plug Luer Male / Female (TP-P-Y)** is classified as **Class Is** as per Rule 2 of Annex IX (Medical Devices Directive 93/42/EEC).

1.14 Medical Device Nomenclature

BD Catalogue Number	GMDN Code	GMDN Term
TP	63614	Luer formatted protective cap
TP-MF		
TP-MF-B		
TP-MF-C		
TP-MF-O		
TP-P-Y		
TP-P-B		

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

1.15 Manufacturing practices

The entire manufacturing and testing processes are following the 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 Medical Articles Co., Ltd. operates a system of internal and external audits to maintain compliance.
- Zibo Qiaosend Medical Articles Co., Ltd. confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.16 Other information

- 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 the products are used for general purpose as a luer cap.
- Good Manufacturing Practices as defined by the EU Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
TP	Male Luer Lock Cap	1	100	1000	No
TP-MF	Male-Female Luer Lock Cap	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
TP-P-Y	Plug Luer Male / Luer Female (Non-Sterile Bulk)	1	100	5000	No
TP-P-B	Plug Luer Male / Luer Female (Sterile)	1	1000	30000	No

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

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

2.2 Packaging materials

BD Catalogue Number	Component	Material
TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O,	Unit Pack	Medical grade paper 60g +PE film 50g
	Shelf Box	Carton
	Shipping Case	Carton
TP-P-Y	Primary Packaging	Plastic Film + Medical Grade Pap
	Inner Bag / Box	Paperboard
	Shipping Case	Kraft Paper + Corrugated Paper
TP-P-B	Primary Packaging	N/A
	Inner Bag / Box	Plastic film
	Shipping Case	Kraft Paper + Corrugated Paper

2.3 Recycled materials in packaging

-Recyclability of Packaging: Based on our ongoing data collection and/or information received from our suppliers, the secondary and tertiary portions of the packaging of the medical devices referenced above are recyclable (at least partially) according to EN 13430:2004.

Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities and some portions of the package may not be recyclable.

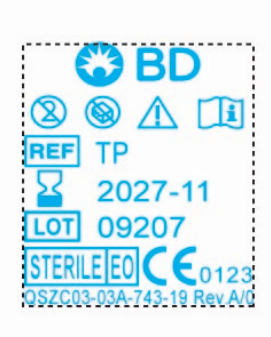
-Recycled Content:

BD Catalogue Number	Packaging Type	Packaging Recycled content	Recyclability
TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O, TP-P-Y	Primary Packaging: Multilayer laminate plastic and paper	0%	Two materials – designed to be peeled apart
			Paper is recyclable
			Multilayer laminate is recyclable through monomer recovery recycling methods
	Secondary Packaging: Folding Carton	30%	Paperboard is recyclable
	Tertiary Packaging: Case Carton	50%	Corrugated box is recyclable
TP-P-B	Primary Packaging: NA	NA	NA
	Secondary Packaging: Polyethylene Bag	0%	Polyethylene is recyclable in communities with this recycling stream
	Tertiary Packaging: Case Carton	50%	Corrugated box is recyclable

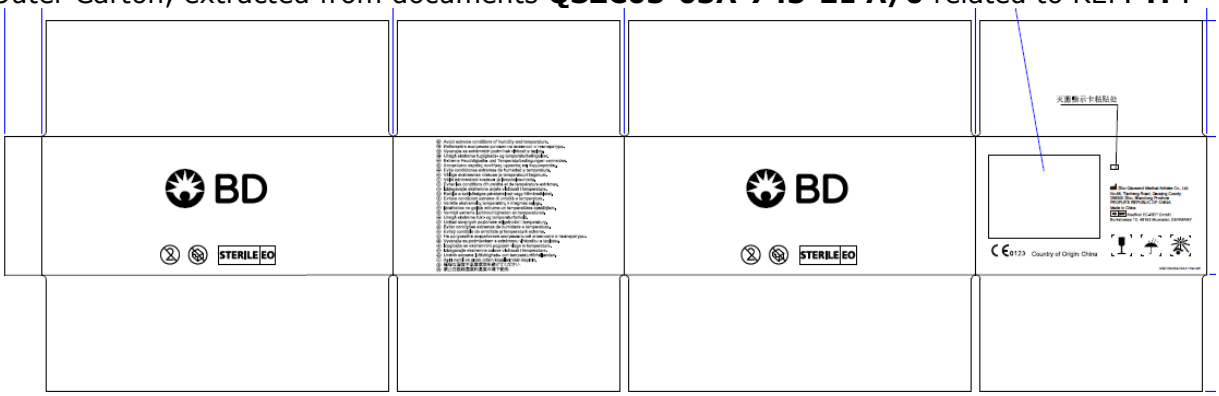
This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

2.4 Examples of labelling

Primary (Unit) label, extracted from document **QSZC03-03A-743-19 Rev.A/0** related to REF. **TP**:

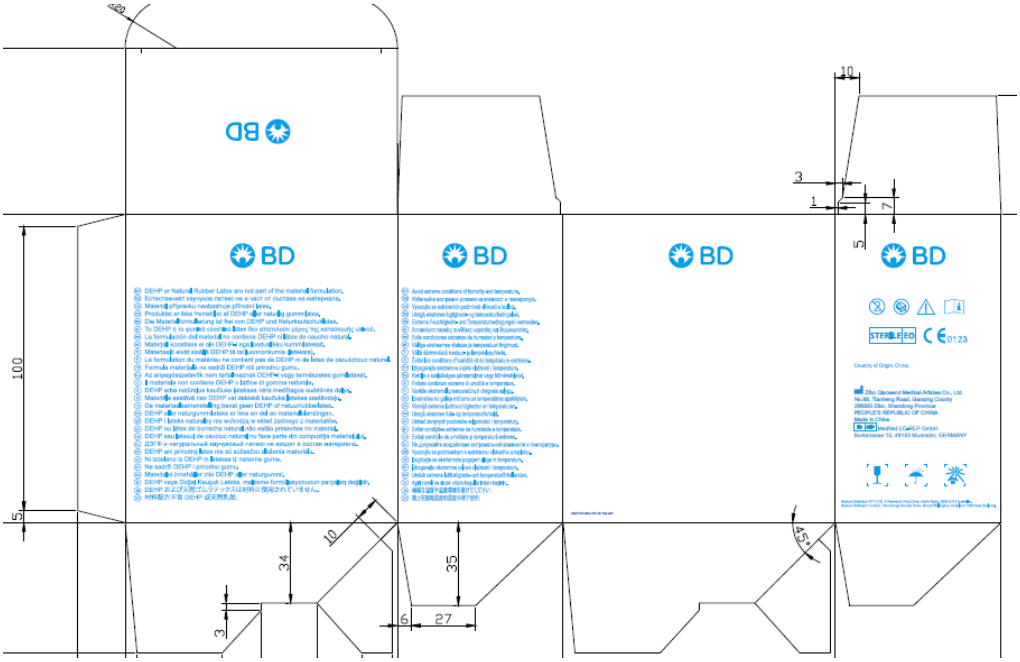


Outer Carton, extracted from documents **QSZC03-03A-743-21 A/0** related to REF. **TP**:

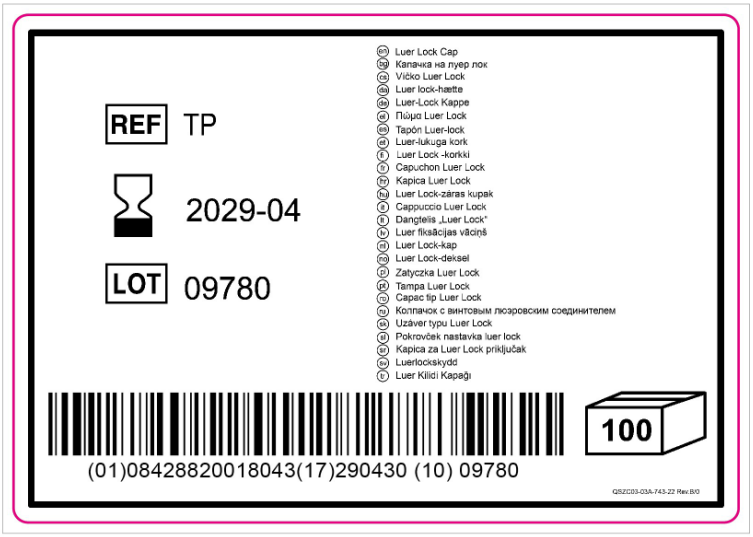


This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

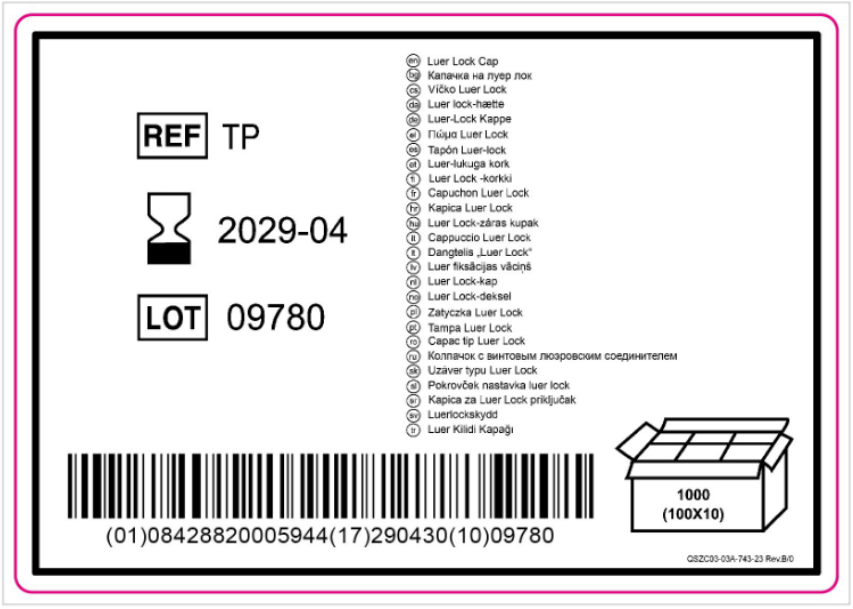
Inner Box extracted from documents **QSZC03-03A-743-20 A/0** related to REF. **TP**:



Shipper Box label, extracted from document **QSZC03-03A-743-22 Rev.B/0** related to reference **TP**:



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.



IFU (English parts only), extracted from document **QSZC03-03A-743-09 Rev.A/0** related to REF. **TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O**:

	en	bg	cs	da	de	el	es	et	fi	fr	hr	hu	it	lt
PHT DEHP	WARNING: Reuse compromises safety and efficacy.	ПРЕДУПРЕЖДЕНИЕ: Повторната употреба излага на риск безопасността и ефикасността.	VAROVÁNÍ: Opětovné použití ohrožuje bezpečnost a účinnost.	ADVARSEL: Genbrug går ud over sikkerheden og anvendelsen.	WARNUNG: Durch Wiederverwendung wird die Sicherheit und Wirksamkeit beeinträchtigt.	ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Η επαναχρησιμοποίηση εκθέτει την ασφάλεια και αποτελεσματικότητα.	ADVERTENCIA: La reutilización compromete la seguridad y eficacia.	HOIATUS: Taaskasutamine ei ole lubatud.	VAROITUS: Uudelleenkäyttö vaikuttaa vaikutukseltaan ja vaarantaa turvallisuuden.	PRÉCAUTION: La réutilisation compromet la sécurité et l'efficacité.	UPOZORENJE: Ponovno korištenje dovodi u pitanje sigurnost i učinkovitost.	FIGYELMEZTETÉS: Az újrafelhasználás veszélyezteti a biztonságot és a hatékonyságot.	AVVERTENZA: Il riutilizzo compromette l'efficacia e la sicurezza.	ĮSPĖJIMAS: Pakartotinis naudojimas naigiamai įtakoja saugumą ir efektyvumą.
	Contains DEHP, a phthalate potentially hazardous in the prolonged treatment of children or pregnant or nursing women. Medical practitioners must balance the benefits of use of this product against foreseeable risks.	Съдържа DEHP – фталат, който е потенциално опасен при продължително лечение на деца, бременни или кърмещи жени. Медицинските специалисти трябва да балансират ползите от употребата на този продукт спрямо предвидимите рискове.	Obsahuje ftalát DEHP, který představuje potenciální riziko při dlouhodobé léčbě dětí, těhotných žen a kojících matek. Zdravotničtí pracovníci musí zvážit jak výhody použití tohoto produktu, tak i předvídatelná rizika.	Indeholder DEHP, et fthalat som anses for at være skadeligt ved længerevarig behandlinger af børn samt gravide eller ammende kvinder. Det er op til det medicinske personale at vægte fordelene ved brugen op imod de forudsigelige risici.	Enthält das Phthalat DEHP, das bei einer längeren Behandlung von Kindern, Schwangeren oder stillenden Frauen gesundheitsschädlich sein kann. Ärzte müssen vor der Verwendung dieses Produkts Nutzen und Risiko sorgfältig gegeneinander abwägen.	Περιέχει DEHP, ένα φθαλικό εστέρα ενδεχομένως επιβλαβή για παιδιά, εγκύους ή θηλάζουσες γυναίκες σε διάρκεια μακροχρόνιας θεραπείας. Οι θεράποντες ιατροί πρέπει να εξισορροπούν τα οφέλη της χρήσης αυτού του προϊόντος έναντι των προβλεπόμενων κινδύνων.	Contiene DEHP, un ftalato potencialmente peligroso en tratamientos prolongados de niños, embarazadas o mujeres en periodo de lactancia. El personal clínico debe valorar los beneficios de utilizar este producto frente a los riesgos previsibles.	Sisältää DEHP-ftalaattia, joka voi olla vaarallista pitkäaikaisessa käytössä lasten tai raskaana olevien tai imettävien naisten hoidossa. Hoitohenkilökunnan tulee arvioida, onko tuotteen käytön tuomat edut ennakoitavissa olevia riskejä suurempia.	Contient du DEHP, un phtalate à risque potentiel en cas d'utilisation prolongée sur des enfants ou des femmes enceintes ou allaitantes. Les médecins doivent mettre en balance les bénéfices de l'utilisation de ce produit avec les risques prévisibles.	Sadrži DEHP, ftalat koji prilikom dugog korištenja može predstavljati potencijalno opasnost za djecu, trudnice ili dojilje. Medicinsko osoblje mora odvagnuti između koristi od korištenja ovog proizvoda i predviđenih rizika.	A termék DEHP-t, vagyis egy olyan ftalátot tartalmaz, amely veszélyes lehet gyermekek, terhes nők, illetve szoptató anyák tartós kezelésére. Az orvosnak mérlegelnie kell a használat előnyét az előreláthatható kockázatokkal szemben.	Contiene DEHP, uno ftalato potenzialmente pericoloso in caso di trattamento prolungato su bambini o donne in stato di gravidanza o allattamento. Il medico davanti valutare i vantaggi derivanti dall'utilizzo di questo prodotto, confrontandoli con i rischi prevedibili.	Sudėtyje yra ftalato DEHP, kuris gali būti pavojingas ilgai gydant vaikus, nėščias ar žindančias moteris. Gydytojai turėtų įvertinti šio produkto vartojimo naudą su numatoma rizika.
DEHP FREE	DEHP FREE	БЕЗ DEHP	NEOBSAHUJE FTALÁTY	DEHP FRI	DEHP-FREI	ΧΩΡΙΣ DEHP	SIN DEHP	DEHP VABA	EI SISÄLLÄ DEHP	SANS DEHP	NE SADRŽI DEHP	DEHP MENTES	DEHP FREE	BE DEHP
LATEX FREE	LATEX FREE	БЕЗ ЛАТЕКС	NEOBSAHUJE LATEX	LATEX FRI	LATEX-FREI	ΧΩΡΙΣ LATEX	SIN LÁTEX	LATEKSIVABA	EI SISÄLLÄ LATEX	SANS LATEX	NE SADRŽI LATEKS	LATEX MENTES	LATEX FREE	BE LATEKSO
PVC FREE	PVC FREE	БЕЗ PVC	NEOBSAHUJE PVC	PVC FRI	PVC-FREI	ΧΩΡΙΣ PVC	SIN PVC	PVC VABA	EI SISÄLLÄ PVC	SANS PVC	NE SADRŽI PVC	PVC MENTES	PVC FREE	BE PVC
Non-pyrogenic	Непирогенен	Nepyrogenní	Pyrogenfri	Pyrogenfrei	Μη πυρογόνο	Apirógeno	Mittepürogeenne	Pürogeenitor	Apyrogeeninen	Non pyrogène	Nije pirogeno	Nem gyógikony	Apirogeno	Nepirogeniškas
Do not use if package is damaged	Да не се използва ако опаковката е увредена	Nepoužívejte, pokud je obal poškozen	Må ikke anvendes hvis pakningen er ødelagt eller åbnet	Nicht verwenden wenn Verpackung beschädigt ist	Μην χρησιμοποιείτε εάν το προϊόν είναι κατεστραμμένο	No usar si el envase está dañado	Ära kasuta katkise pakendi korral	Älä käytä, jos pakkaus on vioittunut	Ne pas utiliser si l'emballage est endommagé	Nemojte koristiti ako je pakiranje oštećeno	Ne használja ha a csomagolás sérült	Non usare se la confezione è danneggiata	Nenaudokite, jei pakuotė pažeista	
NN DROPS PER ML	NN КАПКИ НА ML	POČET KAPEK NA ML	ANTAL DRÅBER PR ML	ANZAHL TROPFEN PRO ML	ΑΡΙΘ ΣΤΑΓΟΝΕΣ ΑΝΑ ML	NN GOTAS POR ML	TILKADE ARV ÜHES M-S	NN GTTML	NN GOUTTES PAR ML	NN KAPI PO ml	NN CSEPP ML-ENKÉNT	NN GOCCE PER ML	LAŠŲ SKAIČIUS MLILITRE	
XX µm FILTER	ФИЛТЪР XX µm	FILTR XX µm	XXµm FILTER	XX µm FILTER	ΦΙΛΤΡΟ XX µm	FILTRO DE XXµm	XX µm FILTER	XX µm:n SUODATIN	FILTRE DE XXµm	FILTAR OD XX µm	XX µm SZŰRŐ	FILTRO DA XXµm	XX µm FILTRAS	
P Alaris™ CC/GP, GW/SE/VP Pump Iris™ 8605/8590 Pump	ISO8536-8—IS—P													

BD

Zibo Qianseré Medical Articles Co, Ltd
NO.268, Tianmeng Road, Gaoqing County
256300 Zibo, Shandong Province
PEOPLE'S REPUBLIC OF CHINA
Made in China

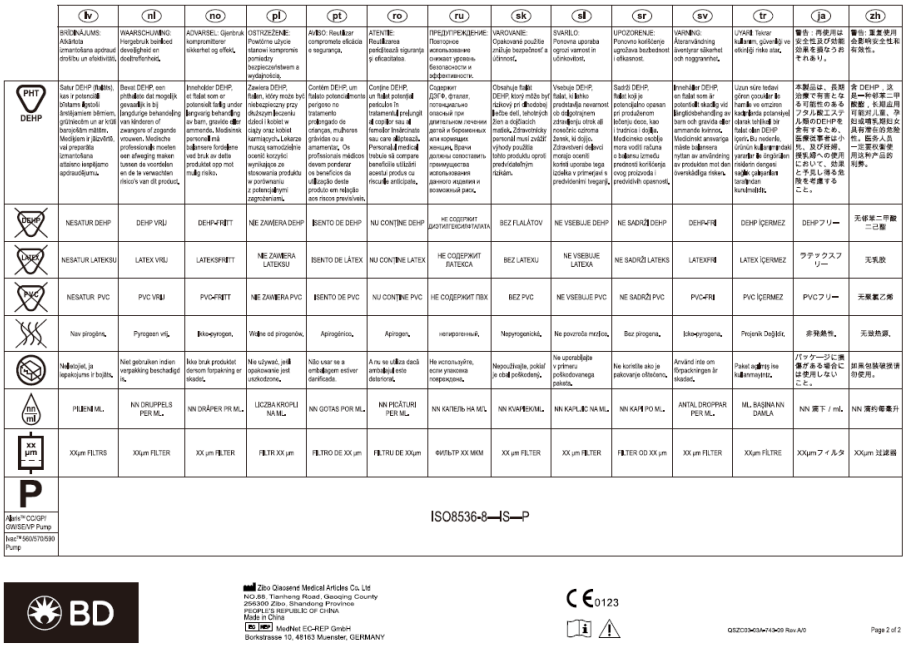
MedNet EC-REP GmbH
Borkstraeße 10, 48163 Muenster, GERMANY

CE 0123

QSZC03A03A743x09 Rev.A/0

Page 1 of 2

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.



	lv	nl	no	pl	pt	ro	ru	sk	sl	sr	sv	tr	ja	zh
	BRĪDINĀJUMS: Atkārtota izmantošana apdraud drošību un efektivitāti.	WAARSCHUWING: Hergebruik beïnvloed deviesveiligheid en doeltreffendheid.	ADVARSEL: Gjenbruk kompromitterer sikkerhet og effekt.	OSTRZEŻENIE: Powtórne użycie stanowi zagrożenie pomiędzy bezpieczeństwem a wydajnością.	AVISO: Reutilizar compromete eficácia e segurança.	ATENȚIE: Reutilizarea pune(ște) sub semnul întrebării siguranța și eficacitatea.	ПРЕДУПРЕЖДЕНИЕ: Повторное использование снижает уровень безопасности и эффективности.	VAROVANIE: Opakované použitie ohrozuje bezpečnosť a účinnosť.	SVARILO: Ponovna uporaba ogrozi varnost in učinkovitost.	UPOZORENJE: Ponovna korišćenje ugrožava bezbednost i efikasnost.	VARNING: Återanvändning äventyrar säkerhet och noggrannhet.	UYARI: Tekrar kullanım, güvenliği ve etkinliği riske atar.	警告：再使用は安全性及び効能効果を損なうおそれがあり。	警告：重复使用会影响安全性和有效性。
PHT DEHP	Satur DEHP (ftalāts), kas ir potenciāli bīstams ķīmiski toksiskām vielām, grūtniecēm un ar krūti barojošām mātēm. Medijiem ir jāizvērtē, vai preparāta izmantošana atbilstoši lietājamo apstākļiem.	Bevat DEHP, een phthalate dat mogelijk gevaarlijk is bij langdurige behandeling van kinderen of zwangere of zogende vrouwen. Medische professionals moeten een afweging maken tussen de voordelen en de te verwachten risico's van dit product.	Inneholder DEHP, et ftalat som er potensielt farlig under langvarig behandling av barn, gravide eller ammende. Medisinsk personell må balansere fordelene ved bruk av dette produktet opp mot mulig risiko.	Zawiera DEHP, ftalan, który może być niebezpieczny przy długoterminowym leczeniu dzieci i kobiet w ciąży oraz kobiet karmiących. Lekarze muszą samodzielnie ocenić korzyści wynikające ze stosowania produktu w porównaniu z potencjalnymi zagrożeniami.	Contém DEHP, um ftalato potencialmente perigoso no tratamento prolongado de crianças, mulheres grávidas ou a amamentar. Os profissionais médicos devem ponderar os benefícios da utilização deste produto em relação aos riscos previsíveis.	Conține DEHP, un ftalat potențial periculos în tratamentul prelungit al copiilor sau al femeilor însărcinate sau care alăptează. Personalul medical trebuie să compare beneficiile utilizării acestui produs cu riscurile anticipate.	Содержит DEHP, потенциально опасный при длительном лечении детей и беременных или кормящих женщин. Врачи должны сопоставить преимущества использования данного изделия и возможный риск.	Obsahuje ftalát DEHP, ktorý môže byť (týkový pri dlhodobej liečbe detí, tehotných žien a dojčiacich matiek. Zdravotnícky personál musí zvážiť výhody použitia tohto produktu oproti predvídateľným rizikám.	Vsebuje DEHP, ftalat, ki lahko predstavlja nevarnost ob daljšnjem zdravljenju otrok ali nosečnic oziroma žensk, ki dojijo. Zdravstveni delavci morajo oceniti koristi uporabe tega izdelka v primerjavi s predvidenimi tveganji.	Sadrži DEHP, ftalat koji je potencijalno opasan pri produženom lečenju dece, kao i trudnica i dojilja. Medicinsko osoblje mora vršiti ocenu o balansu između prednosti korišćenja ovog proizvoda i predviđenih opasnosti.	Innehåller DEHP, en ftalat som är potentiellt skadlig vid långtidsbehandling av barn och gravida eller ammande kvinnor. Medicinsk anvariga måste balansera nyttan av användning av produkten mot den overskådliga risken.	Uzun süre tedavi görün çocuklar ile hamile ve emziren kadınlarda potansiyel olarak tehlikeli bir ftalat olan DEHP içerir. Bu nedenle, ürünün kullanımından yararlar ile öngörülen risklerin dengesi sağlık çalışanları tarafından kurulmalıdır.	本製品は、長期治療で有害となる可能性のあるフタル酸エステル類のDEHPを含有するため、医療従事者は小児、及び妊婦、授乳婦への使用において、効果と予見し得る危険を考慮すること。	含 DEHP，这是一种邻苯二甲酸酯，长期应用可能对儿童、孕妇或哺乳期妇女具有潜在的危险性。医务人员一定要权衡使用这种产品的利弊。
DEHP	NESATUR DEHP	DEHP VRIJ	DEHP-FRITT	NIE ZAWIERA DEHP	ISENTO DE DEHP	NU CONȚINE DEHP	НЕ СОДЕРЖИТ ДИЭТИЛГЕКСИЛФТАЛАТА	BEZ FTALÁTOV	NE VSEBUJE DEHP	NE SADRŽI DEHP	DEHP-FRI	DEHP İÇERMEZ	DEHPフリー	无邻苯二甲酸二己酯
LATEX	NESATUR LATEKSU	LATEX VRIJ	LATEKSFRITT	NIE ZAWIERA LATEKSU	ISENTO DE LÁTEX	NU CONȚINE LATEX	НЕ СОДЕРЖИТ ЛАТЕКСА	BEZ LATEXU	NE VSEBUJE LATEXA	NE SADRŽI LATEKS	LATEXFRI	LATEX İÇERMEZ	ラテックスフリー	无乳胶
PVC	NESATUR PVC	PVC VRIJ	PVC-FRITT	NIE ZAWIERA PVC	ISENTO DE PVC	NU CONȚINE PVC	НЕ СОДЕРЖИТ ПВХ	BEZ PVC	NE VSEBUJE PVC	NE SADRŽI PVC	PVC-FRI	PVC İÇERMEZ	PVCフリー	无聚氯乙烯
	Nav pirogēna.	Pyrogeen vrij.	Ikke-pyrogen.	Wolne od pirogenów.	Apirogénico.	Apirogen.	непирогенный.	Nepyrogenické.	Ne povzroča mrzlice.	Bez pirogena.	Icke-pyrogena.	Pirojenik Değildir.	非発熱性。	无致热源。
	Nelietojiet, ja iepakojums ir bojāts.	Niet gebruiken indien verpakking beschadigd is.	Ikke bruk produktet dersom forpakning er skadet.	Nie używać, jeśli opakowanie jest uszkodzone.	Não usar se a embalagem estiver danificada.	A nu se utiliza dacă ambalajul este deteriorat.	Не использовать, если упаковка повреждена.	Nepoužívajte, pokiaľ je obal poškodený.	Ne uporabljajte v primeru poškodovanega pakeja.	Ne koristite ako je pakovanje oštećeno.	Använd inte om förpackningen är skadad.	Paket açılmış ise kullanmayınız.	パッケージに損傷がある場合には使用しないこと。	如果包装破损请勿使用。
	PILIENI ML.	NN DRUPPELS PER ML.	NN DRÅPER PR ML.	UCZBA KROPLI NA ML.	NN GOTAS POR ML.	NN PICĂTURI PER ML.	NN КАПЕЛЬ НА МЛ.	NN KVAPIEK/ML.	NN KAPLJIC NA ML.	NN KAPI PO ML.	ANTAL DROPPAR PER ML.	ML. BAŞINA NN DAMLA	NN 滴下 / ml.	NN 滴约每毫升
	XXµm FILTRS	XXµm FILTER	XX µm FILTER	FILTR XX µm	FILTRO DE XX µm	FILTRU DE XXµm	ФИЛЬТР XX МКМ	XX µm FILTER	XX µm FILTER	FILTER OD XX µm	XX µm FILTER	XXµm FİLTRE	XXµmフィルタ	XXµm 过滤器
	P													
Alaris™ CC/GP/ GW/SE/VP Pump Iroc™ 560/570/580 Pump:	ISO8536-8—IS—P													

BD

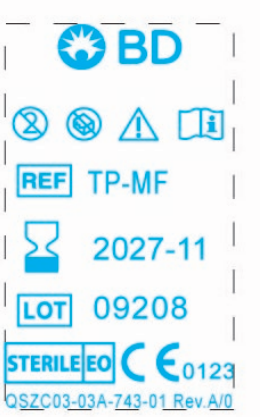
Zibo Qiaosenji Medical Articles Co. Ltd
NO.88, Tianheng Road, Gaoqing County
256300 Zibo, Shandong Province
PEOPLE'S REPUBLIC OF CHINA
Made in China
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

CE 0123

QSZC03-03A-743-01 Rev.A/0

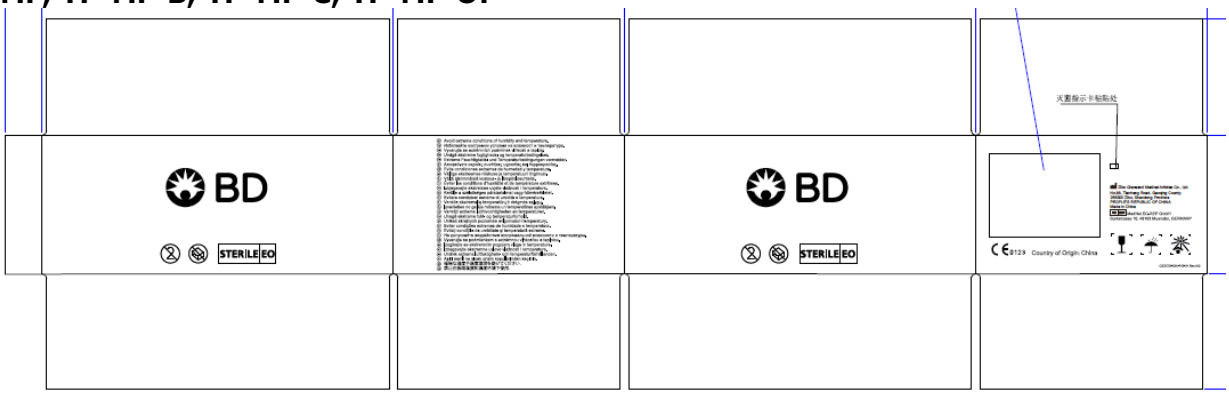
Page 2 of 2

Primary (Unit) label, extracted from document **QSZC03-03A-743-01 Rev.A/0** related to REF. **TP-MF:**

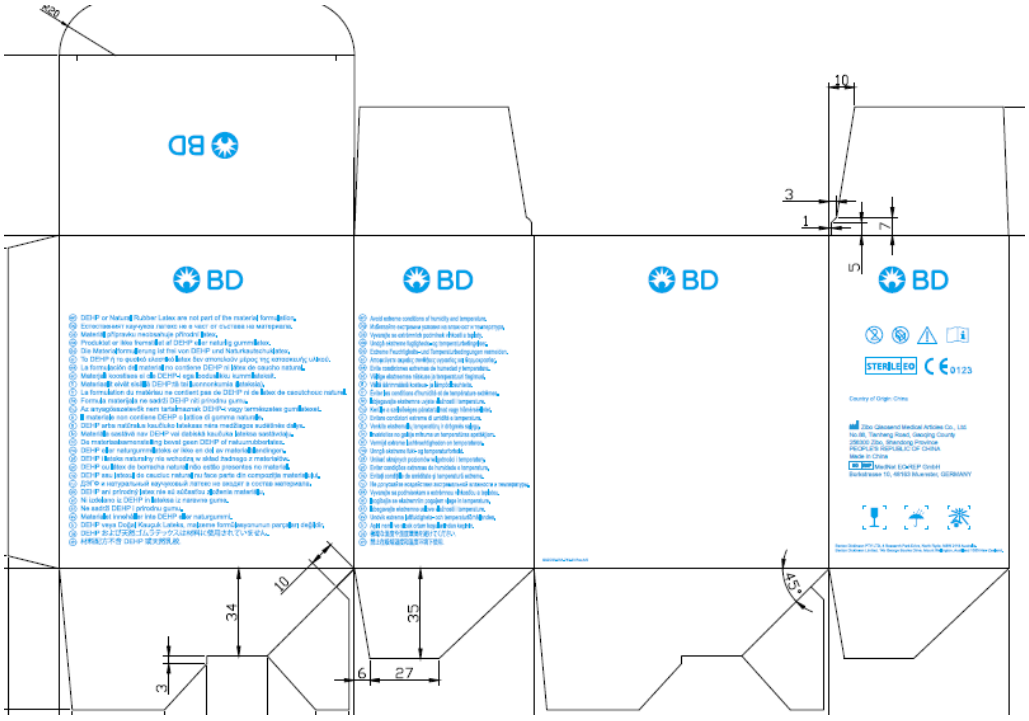


This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Outer Carton, extracted from documents **QSZC03-03A-743-04 A/0** related to REF. **TP-MF, TP-MF-B, TP-MF-C, TP-MF-O:**



Inner Box extracted from documents **QSZC03-03A-743-03 A/0** related to REF. **TP-MF, TP-MF-B, TP-MF-C, TP-MF-O:**



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shipper Box label, extracted from document **QSZC03-03A-743-05 Rev.A/0** related to REF. **TP-MF:**



Primary (Unit) label, extracted from document **QSZC03-03A-743-02 Rev.A/0** related to REF. **TP-MF-B**:



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shipper Box label, extracted from document **QSZC03-03A-743-07 Rev.A/0** related to REF. **TP-MF-B:**



Primary (Unit) label, extracted from document **QSZC03-03A-743-13 Rev.A/0** related to REF. **TP-MF-C**:

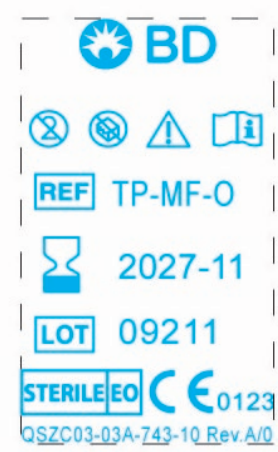


This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shipper Box label, extracted from document **QSZC03-03A-743-14 Rev.A/0** related to REF. **TP-MF-C:**



Primary (Unit) label, extracted from document **QSZC03-03A-743-10 Rev.A/0** related to REF. **TP-MF-O**:



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shipper Box label, extracted from document **QSZC03-03A-743-11 Rev.A/0** related to REF. **TP-MF-O:**

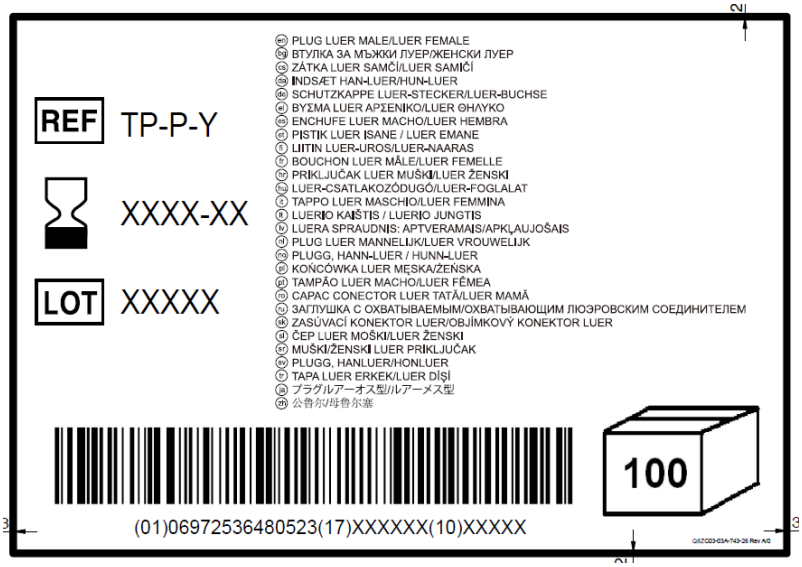


Primary (Unit) label, extracted from document **QSZC03-03A-743-25 Rev.A/0** related to REF. **TP-P-Y**:



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shelf box, extracted from documents **QSZC03-03A-743-26 A/0** related to REF. **TP-P-Y:**

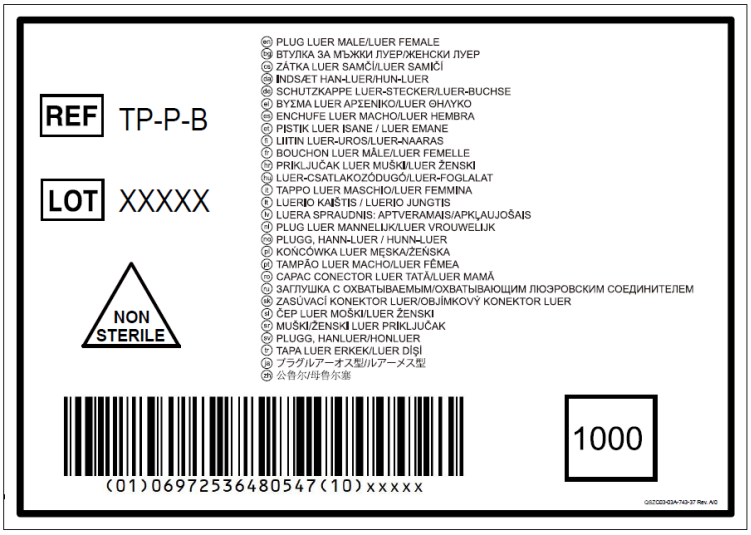


Shipper label extracted from document **QSZC03-03A-743-27 A/0** related to REF. **TP-P-Y:**

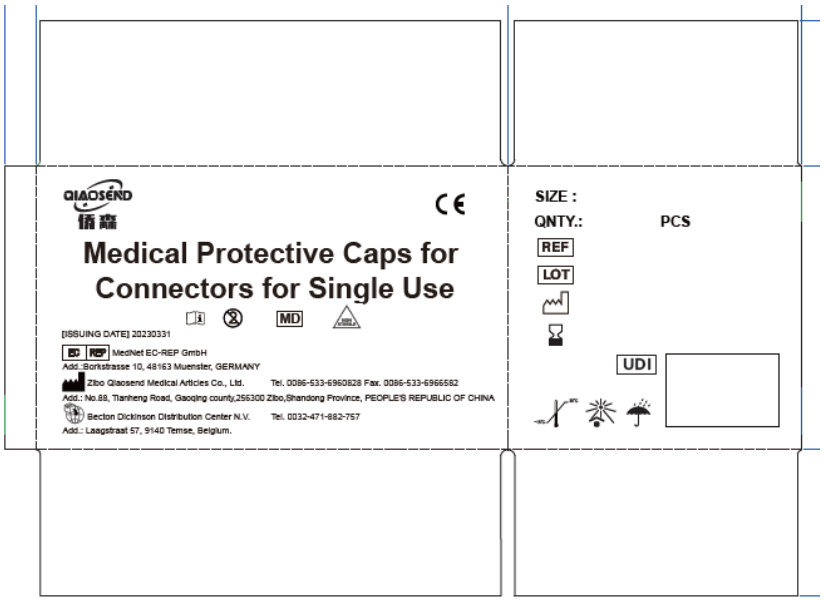


This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shelf bag label, extracted from documents **QSZC03-03A-743-37 A/0** related to REF. **TP-P-B:**

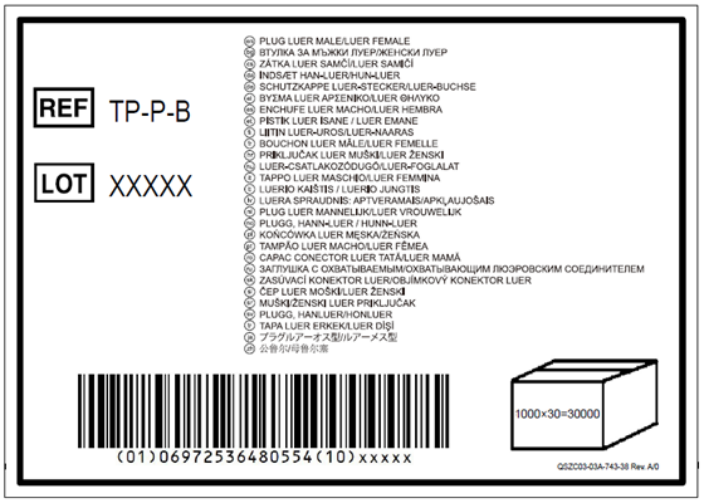


Shipper Box extracted from documents **QSZC03-03A-008-09-03-en A/0** related to REF. **TP-P-B:**



This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.

Shipper label, extracted from document **QSZC03-03A-743-38 Rev.A/0** related to REF. **TP-P-B:**



REVISION	CHANGE SUMMARY
01	Initial release according to Initial release according to new template V200QARA-SWI-01-A
02	- Update to new template EMEA-SOP039-F1_Rev.02 based on most updated technical documentation from Zibo Qiaosend Medical Articles Co., Ltd. - Updated information about SKUs TP-P-B and TP-P-Y - Addition of following SKUs: TP, TP-MF, TP-MF-B, TP-MF-C, TP-MF-O

This document is BECTON DICKINSON property and cannot be modified by any third party
The content of this document may be subject to change without notice.