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

BD® MaxZero™ Pressure Rated Extension Sets
Sterile, Single-use

Product codes: MZ5301, MZ5302, MZ5303, MZ5304, MZ5305, MZ5306, MZ5307, MZ5309, MZ5310

BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland

TDS number: V201-181 Rev. 01
Veeva Vault number: BD-141724
2025-June

1. General Information

1.1 Intended purpose

The MaxZero™ Extension Sets are intended to provide a conduit for administering fluids into the body, enabling connection to reservoirs and an invasive puncture device.

1.2 Intended User

The MaxZero™ Extension Sets are CE certified under MDD. BD is transitioning to the Medical Device Regulation (MDR), and as the information in this section is the requirement of MDR, it is still not available. The Technical Data Sheet (TDS) will be updated once the transition to MDR is completed.

1.3 General Medical Devices description

The MaxZero™ Extension Sets are disposable IV lines used to administer fluids, drugs, nutrition (TPN – Total Parenteral Nutrition), lipids & blood to the human body. The IV administration set may contain a combination of various IV set components specifically designed or selected to meet user needs. The administration sets vary in length, configuration and priming volume.

Figure 1: MZ5301 and MZ5302

Figure 2: MZ5303

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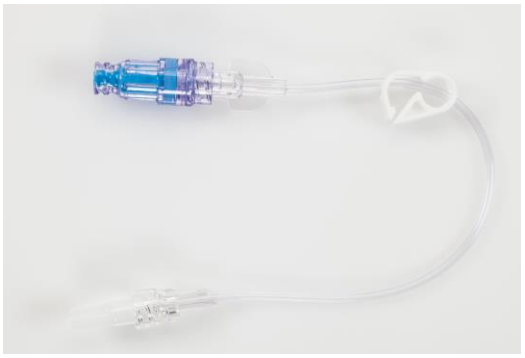

Figure 3: MZ5304

Figure 4: MZ5305

Figure 5: MZ5306

Figure 6: MZ5307

Figure 7: MZ5309

Figure 8: MZ5310

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BD Catalogue Number	BD Product Description	Gravity Use	Pump Use	NFC (Needle Free Connector)	Number of NFC	Tube Length (cm)	Total Length (cm)	Average Gravity Flow Rate (L/H)	Priming Volume (mL)
MZ5301	BD MaxZero™. Minibore pressure rated extension set, IV connector	Yes	Yes	Bonded	1	12.7	17.8	4.01	0.4
MZ5302	BD MaxZero™. Minibore pressure rated extension set, removable IV connector	Yes	Yes	Removable	1	13.3	17.8	3.34	0.4
MZ5303	BD MaxZero™. Pressure rated extension set, IV connector	Yes	Yes	Bonded	1	12.7	17.8	6.20	0.5
MZ5304	BD MaxZero™. Pressure rated extension set, removable IV connector	Yes	Yes	Removable	1	12.7	17.8	6.20	0.5
MZ5305	BD MaxZero™. Pressure rated extension set, IV connector, no clamp	Yes	Yes	Bonded	1	12.7	17.8	6.35	0.5
MZ5306	BD MaxZero™. Minibore pressure rated extension set, IV connector, no clamp	Yes	Yes	Bonded	1	12.7	17.8	4.14	0.4
MZ5307	BD MaxZero™. Minibore bi-fuse pressure rated extension set, 2 IV connectors	Yes	Yes	Bonded	2	12.7	17.8	3.17	0.8
MZ5309	BD MaxZero™. Pressure rated extension set, IV connector	Yes	Yes	Bonded	1	14.6	17.8	6.20	0.5
MZ5310	BD MaxZero™. Pressure rated extension set, removable IV connector	Yes	Yes	Removable	1	12.7	17.8	6.20	0.5

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BD Catalogue Number	Tube Diameter		Change Interval	Pressure Rating	Drug Compatibility	Disinfectant Compatibility	Male Luer Type	Clamp Type	MRI/CT compatibility*
	Inner (mm)	Outer (mm)							
MZ5301	1	2	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl Alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Slide	Yes
MZ5302	1	2	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Slide	Yes
MZ5303	1.5	3.7	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Pinch	Yes
MZ5304	1.5	3.7	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Pinch	Yes
MZ5305	1.5	3.7	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	None	Yes
MZ5306	1	2	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	None	Yes
MZ5307	1	2	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Slide	Yes
MZ5309	1.5	3.7	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Slide	Yes
MZ5310	1.5	3.7	7 days/200 activations	325 PSI; 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	Spin Lock	Slide	Yes

*MRI (Magnetic Resonance Imaging) // CT (Computed Tomography)

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.

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1.4 Certification

BD Catalogue Number	BD Legal Manufacturer and ISO 13485 Certification	CE/UKCA Certificate Number and Notified Body Acronym and Number	BD Manufacturing Site (Country of Origin) And ISO 13485 Certification	EC Representative (if applicable)
MZ5301	Name and Address: BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland ISO 13485 Certificate No.: MD 71300	CE certified with BSI (2797) MDD Certificate No.: 502238 UKCA certified: N/A	Name and Address: Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351, Parque Industrial, El Florido Seccion Vistas 1, Tijuana, Baja California, CP 22244, Mexico. ISO 13485 Certificate No.: FM 688319 Name and Address: Sistemas Medicos Alaris S.A De C.V. Blvd Antonio Quiroga No. 107-H Col Villa Sauces Hermosillo, Sonora C.P. 83174, Mexico ISO 13485 Certificate No.: FM 748612	Name and Address: EC Representative: Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
MZ5302				
MZ5303				
MZ5304				
MZ5305				
MZ5306				
MZ5307				
MZ5309				
MZ5310				

1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers **MZ5301, MZ5302, MZ5303, MZ5304, MZ5305, MZ5306, MZ5307, MZ5309** and **MZ5310** referenced in this document are CE-certified under the Medical Device Directive (MDD). BD is transitioning to the Medical Device Regulation (MDR) and, as the information in this section is a MDR requirement, it is still not available. The Technical Data Sheet will be updated once the transition to MDR is completed.

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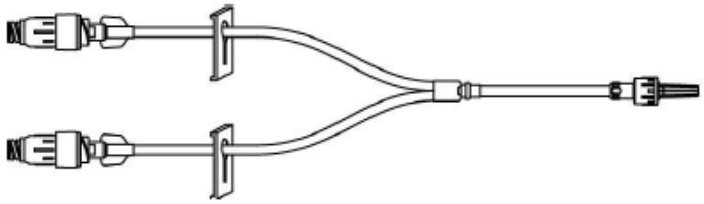
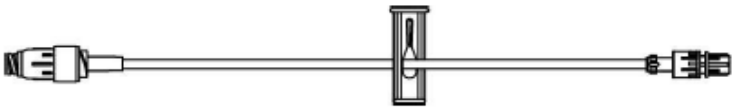
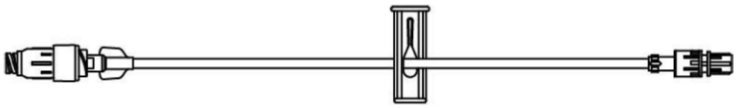
1.6 Materials

BD Catalogue Number	Drawings
MZ5301	
MZ5302	
MZ5303, MZ5304	
MZ5305	
MZ5306	
MZ5307	
MZ5309	
MZ5310	

BD Catalogue Number	Component		Material
MZ5301	MaxZero™ Microbore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		Polyvinyl chloride (PVC) with plasticizer DOA (Dioctyl adipate)
	Male Luer and Cap, OR		Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene (MABS)

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	Luer with Cap		Low-Density Polyethylene (LDPE)
	Slide clamp White		High-density polyethylene (HDPE)
MZ5302	MaxZero™ (NAC*) connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Male Luer and Cap, OR		MABS
	Luer with Cap		LDPE
	Microbore Female Luer		Copolyester
	Slide clamp White		HDPE
MZ5303	MaxZero™ Standard Bore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Spin Free Assembly, macrobore		Stainless Steel or equivalent
	Luer Lock macro	Hub	MABS
		Luer slip	MABS
		Cap	LDPE
	Standard Bore Pinch clamp–White		Polypropylene
MZ5304	MaxZero™ (NAC*) connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Spin Free Assembly, macrobore		Stainless Steel or equivalent
	Luer Lock macro	Hub	MABS
		Luer slip	MABS
		Cap	LDPE
	Standard Bore Female Luer		Copolyester
	Standard Bore Pinch clamp–White		Polypropylene
MZ5305	MaxZero™ Standard Bore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Spin Free Assembly, macrobore		Stainless Steel or equivalent
	Luer Lock macro	Hub	MABS
		Luer slip	MABS
		Cap	LDPE
MZ5306	MaxZero™ Microbore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Male Luer and Cap, OR		MABS
	Luer with Cap		LDPE
MZ5307	MaxZero™ Microbore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A

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		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Male Luer and Cap, OR		MABS
	Luer with Cap		LDPE
	Micro bifurcated Connector		Polycarbonate
	Slide clamp White		HDPE
MZ5309	MaxZero™ Standard Bore connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Spin Free Assembly, macrobore		Stainless Steel or equivalent
	Luer Lock macro	Hub	MABS
		Luer slip	MABS
		Cap	LDPE
	Slide clamp – Blue		HDPE
MZ5310	MaxZero™ (NAC*) connector	Top Housing	Polycarbonate
		Base Housing	Polycarbonate
		Valve	Elastosil LR3003/70A
		Colorant	Blue Colorant
	Tubing		PVC with DOA
	Spin Free Assembly, macrobore		Stainless Steel or equivalent
	Luer Lock macro	Hub	MABS
		Luer slip	MABS
		Cap	LDPE
	Standard Bore Female Luer		Copolyester
	Slide clamp – Blue		HDPE

*Needleless Access Connector

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 2 April 2025, BD 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),

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Material	Comment
	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.
Bisphenol A (BPA)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 2 April 2025, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). There are polycarbonate components in these products. Bisphenol A (BPA), CAS# 80-05-7, is an organic compound that is a chemical building block for polycarbonate. Based on information from our suppliers and BD, the BPA level is less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 2 April 2025, BD has not identified any 2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetra-decanoate (DOTE) (CAS# 15571-58-1) in the article and packaging with the product numbers referenced above, in an individual concentration above 0.1% w/w. **For SKU# MZ5307:** Based on our ongoing data collection efforts and/or information received from our suppliers as per 2 April 2025, BD has not identified any 2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetra-decanoate (DOTE) (CAS# 15571-58-1) in the article and packaging with the product number as referenced above, in an individual concentration above 0.1% w/w. There is a Bifurcated Adapter component with rigid polyvinyl chloride (PVC) in this product. Based on BD testing results, the DOTE (CAS# 15571-58-1) contained in this article has been confirmed to be less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No REACH SVHC declaration is required.
RoHS directive, heavy metals, brominated flame retardants	It is BD'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 2 April 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products.
Class 1A and 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) & Endocrine-Disrupting (ED) Substances	BD 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 2 April 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

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Material	Comment
	5(3) of Regulation EU 528/2012. Please note that the data collection process is continuing.
Latex (euMDR Annex I Sections 13.3 and 23.4(s))	Based on our ongoing data collection efforts and/or information received from our suppliers as per 2 April 2025, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
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).
Heavy Metals in Packaging	Based on our ongoing data collection efforts and/or information received by our suppliers as per 2 April 2025, the products (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).
Polyvinyl Chloride (PVC)	**For SKU# MZ5307:** The medical device referenced above has been designed and manufactured with PVC raw material in the Tubing and Bifurcated Adapter. **For SKU# MZ5301, MZ5302, MZ5303, MZ5304, MZ5305, MZ5306, MZ5309, MZ5310:** The medical devices referenced above have been designed and manufactured with PVC raw material in the Tubing component.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 2 April 2025, BD 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

BD Medical 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

The **MaxZero™ Extension Sets** are sterilized using Irradiation (R) as per standard BS EN ISO 11137-1 Sterilization of health care products Radiation.

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1.11 Shelf life and storage conditions

The **MaxZero™ Extension Sets**' shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
MaxZero™ Extension Sets has a shelf life of 3 years.
BD recommends to store in a dry and warm place, not exposed to strong light.
Single use clarification: MaxZero™ extension sets are placed on the market as sterile single use devices. Reuse constitutes misuse.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title
Harmonized Standard Reference	
BS EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices.
BS EN 1041:2008 +A1:2013	Information supplied by the manufacturer with the medical devices.
BS EN ISO 1135-4:2015/Corr 2016	Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed.
BS EN ISO 1135-5:2015	Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus.
BS EN ISO 10993 1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
BS EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.
BS EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
BS EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
BS EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
BS EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
BS EN ISO 11137-1:2015 +A2 2019	Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11137-2:2015/Amd1:2023	Sterilization of health care products Radiation Part 2: Establishing the sterilization dose
BS EN ISO 11607-1:2020+A11:2022	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems.
BS EN ISO 11607-2:2020+A11:2022	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes.
BS EN ISO 11737-2:2020	Sterilization of medical devices Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
BS EN ISO 13485:2016+A11:2021	Medical devices Quality management systems Requirements for regulatory purposes.
BS EN ISO 14971:2019+A11:2021	Medical Devices Application of risk management to medical devices.

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Standard reference number	Title
BS EN ISO 15223-1:2016/AC:2017	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.
BS EN 15986:2011	Symbol for use in the labelling of medical devices Requirements for labelling of medical devices containing phthalates.
BS EN 20594-1:1993/AC:1996	Conical fittings with a 6%(Luer) taper for syringes, needles and other certain medical equipment part 1: General requirements
ISO 594-1:1986	Conical fittings with a 6%(Luer) taper for syringes, needles and other certain medical equipment - part 1: General requirements
ISO 594-2:1998	Conical fittings with a 6%(Luer) taper for syringes, needles and other certain medical equipment - part 2: Lock fittings
ISO 14001:2015	Environmental Management System*
Non-Harmonised Standard Reference	
BS EN ISO 8536-4:2013 +A1:2013	Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed.
BS EN ISO 8536-8:2015	Infusion equipment for medical use Part 8: Infusion sets for single use with pressure infusion apparatus.
BS EN ISO 8536-9:2015	Infusion equipment for medical use Part 9: Fluid lines for single use with pressure infusion equipment.
BS EN ISO 8536-10:2015	Infusion equipment for medical use Part 10: Accessories for fluid lines for single use with pressure infusion equipment.
BS EN ISO 10993-2:2022	Biological evaluation of medical devices Part 2: Animal welfare requirements
BS EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.
BS EN ISO 10993-16:2017	Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables
BS EN ISO 10993-18:2020+A1:2023	Biological evaluation of medical devices Part 18: Chemical characterization of materials
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration.
BS EN ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.
BS EN ISO 14644-5:2004	Cleanrooms and associated controlled environments – Part 5: Operations.
BS EN ISO 11137-3:2017	Sterilization of health care products Radiation Part 3: Guidance on dosimetric aspects of development, validation and routine control
BS EN ISO 11737-1:2018+A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product.
ISTA-1A - 2014 Edition	Non-Simulation Integrity Performance Tests, Packaged- Products weighing 150 lb (68 kg) or Less.
ISTA-2A - 2012 Edition	Partial-Simulation Performance Tests, Packaged-Products weighing 150 lb (68 kg) or Less.

*Sistemas Medicos Alaris S.A de C.V (Tijuana) complies with ISO14001:2015.

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

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1.13 Classification

MaxZero™ Extension Sets are EC Product Class IIa in accordance with Council Directive 93/42/EEC, Annex IX, Rule 2.

1.14 Medical Device Nomenclature

GMDN Code: 12170
GMDN Term: Intravenous administration tubing extension set

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.
- BD operates a system of internal and external audits to maintain compliance.
- BD 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 BD 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 EU Pharmaceutical is not applicable for Medical Devices.

- The following directives are not applicable, see rationale below:

Directive	Number	Applicability
RoHS2 Directive	2011/65/EU	Not Applicable as the directive is for the Restriction of the use of certain hazardous substances in electrical and electronic equipment
EMC Directive	2014/30/EU	Does not apply

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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*
MZ5301	BD MaxZero™. Minibore pressure rated extension set, IV connector	1	N/A	50	Yes
MZ5302	BD MaxZero™. Minibore pressure rated extension set, removable IV connector	1	N/A	50	Yes
MZ5303	BD MaxZero™. Pressure rated extension set, IV connector	1	N/A	50	Yes
MZ5304	BD MaxZero™. Pressure rated extension set, removable IV connector	1	N/A	50	Yes
MZ5305	BD MaxZero™. Pressure rated extension set, IV connector, no clamp	1	50	600	Yes
MZ5306	BD MaxZero™. Minibore pressure rated extension set, IV connector, no clamp	1	50	600	Yes
MZ5307	BD MaxZero™. Minibore bi-fuse pressure rated extension set, 2 IV connectors	1	N/A	50	Yes
MZ5309	BD MaxZero™. Pressure rated extension set, IV connector	1	50	600	Yes
MZ5310	BD MaxZero™. Pressure rated extension set, removable IV connector	1	50	600	Yes

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

2.2 Packaging materials

BD Catalogue Number	Component	Material
MZ5301 MZ5302 MZ5303 MZ5304 MZ5305 MZ5306 MZ5307 MZ5309 MZ5310	Top Web	FFS (Form Fill Seal) packaging Tyvek
	Bottom Web	FFS packaging, 0.060 thick x 322mm wide film
	Shelf Carton and Case Carton	Cardboard

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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
MZ5301, MZ5302, MZ5303, MZ5304, MZ5307	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: Shelf Carton	Unknown	Cardboard is recyclable
	Tertiary Packaging: NA	NA	NA
MZ5305, MZ5306, MZ5309, MZ5310	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: Shelf Carton	Unknown	Cardboard is recyclable
	Tertiary Packaging: case carton	Unknown	Corrugated box is recyclable

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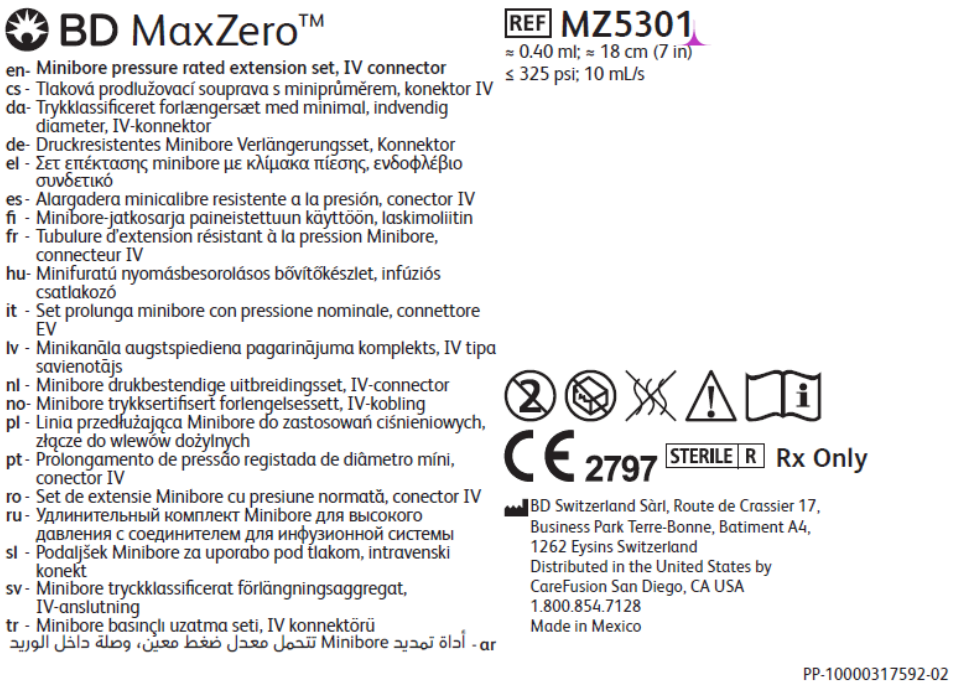
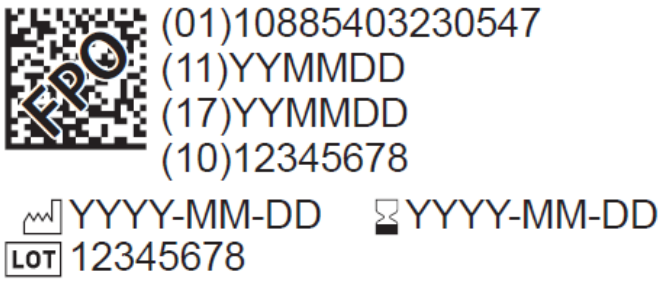
2.4 Examples of labelling

Pouch Label extracted from document TAHITI-10000317592, revision 02 / version B, related to reference MZ5301:



In Line Print Label extracted from document TAHITI-10000324330, revision 03 / version C, related to reference MZ5301:



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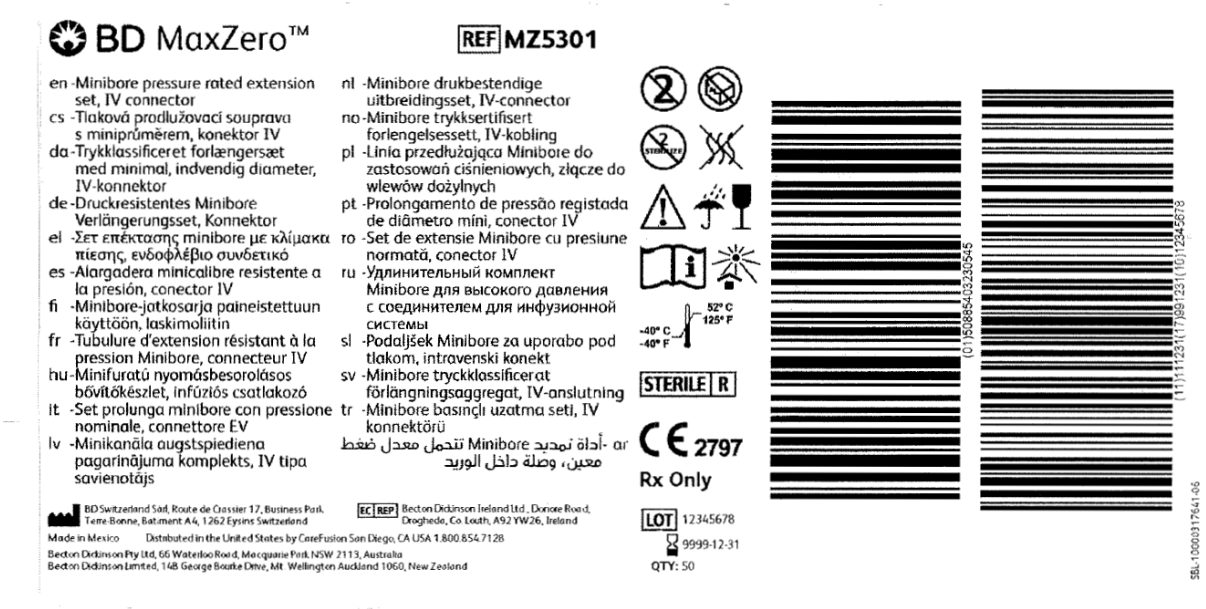
Shipper Label extracted from document TAHITI-10000317641, revision 06 / version E, related to reference MZ5301:



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Direction for Use (DFU) insert (English part only) extracted from document 10000583383, revision 01 / version A, related to reference MZ5301:

For the whole document, where other languages are included, please refer to: eifu.bd.com

BD MaxZero™ multi-fuse pressure rated extension set with needleless connector(s)

INDICATIONS FOR USE: The MaxZero™ multi-fuse extension set with needleless connector(s) is for single patient use only. The extension set can be used for direct injection, intermittent infusion, continuous infusion, or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.

DIRECTIONS: Use aseptic technique.

1. Peel package open and remove set. Verify integrity of all connections (tighten if necessary).
2. Prime extension set per facility protocol, taking care to invert connector(s) and extension set to expel all air.
3. Remove the protective cover and attach to desired venous access device.
4. Prior to every access, always scrub the top of the connector(s) with an appropriate antiseptic and allow to dry.
5. Attach luer from primed IV set or syringe to the connector(s). If luer is a two piece spin collar, first pull back the collar and insert luer with a straight in motion and rotate 1/4 turn clockwise; then push the spin collar forward and tighten. If syringe has a luer slip, insert and rotate 1/4 turn clockwise to secure connection. Do not leave luer slip unattended due to potential for disconnection.
6. Flush the connector(s) after each use with normal saline or in accordance with facility protocol.
7. When disconnecting a luer-lock or luer-slip syringe or tubing set from the MaxZero™ connector, carefully rotate the luer counter clockwise a 360 degree turn or until disconnected using a controlled motion, to minimize fluid escaping. Wipe connector surface dry by swabbing surface after disconnection.
8. For subsequent connections, repeat from step 4.
9. Change according to the facility protocol or in accordance with current recognized guidelines for IV therapy, such as every 7 days or 200 activations.
10. For use with pressure, this product must be secured to other luer lock devices also rated for use with pressure up to 325 psi.

⚠CAUTIONS AND RECOMMENDATIONS:

- The device should not be used with needles, blunt cannula systems, non ISO luer connections, or luer connections with visible defects. Doing so may result in leakage and/or failure of the device.
- For proper use, clinicians must be familiar with and trained in the use of the device. Its use should be preceded by an established facility protocol.
- The device should be disinfected with an appropriate antiseptic agent, such as a 3-second scrub with 70% IPA, prior to each access.
- Trace all lines prior to administration.
- Clamp line when not in use as a safety precaution.
- Failure to properly prime the device can result in reflux.
- To dispose of this device adhere to local, state, federal and/or other governing regulations for medical device waste disposal and or bio hazards waste disposal.
- Sterile disposable single patient use device may be accessed multiple times per hospital protocol. Reuse, reprocessing or re-sterilizing may lead to patient infection or other illness/injury.

CE 2797 STERILE R

Rx Only

DEHP or Natural Rubber Latex are not part of the material formulation.

BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland
Distributed in the United States by CareFusion San Diego, CA USA 1.800.854.7128
Made in Mexico
630-03010 Rev 00

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Symbols Glossary

http://www.bd.com/symbols-glossary


Do not re-use

Sterilized using irradiation


Keep away from sunlight


Consult instructions for use


Do not use if package is damaged

Catalogue number


Fragile, handle with care

Conformité Européene Notified Body 2797


Nonpyrogenic

Batch code


Temperature limit


Manufacturer


Do not resterilize

Use-by date


Keep dry


Caution

REVISION	CHANGE SUMMARY
01	Initial release according to TDS template EMEA-SOP039-F1, revision 02 based on Technical Documentation STED308 Revision 52 published in September 2024.

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