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

BD® Alaris™ Products. SmartSite™ Needle-free Valve.
Sterile, Single-use
Product code: MFX2250EV

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

BD® SmartSite™ Needle-free System.
Sterile, Single-use
Product code: MFX2309EV

TDS number: V201-085 Rev. 02
Veeva Vault number: BD-146892
2025-May

1. General Information

1.1 Intended purpose

The intended use of the SmartSite™ Needle-free Valve and SmartSite™ Needle-free System set range is to provide a conduit for fluids intended for infusion enabling connection to a fluid reservoir and a venous-puncture device.
Gravity alone provides the source of energy for infusion.

1.2 Intended User

The products above referenced are CE certified under Medical Device Directive (MDD). BD is transitioning to the Medical Device Regulation (MDR), and as the information in this section is a 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

To provide a conduit for fluids intended for intra-venous infusion enabling connection to a fluid reservoir and a venous-puncture device. Gravity and gravity alone provides the source of energy for infusion.



Figure 1: MFX2250EV



Figure 2: MFX2309EV

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BD Catalogue Number	BD Product Description	Tube Length (cm)	Total Length (cm)	Priming Volume (mL)	Tube Inner Diameter (mm)	Tube Outer Diameter (mm)
MFX2250EV	Alaris™ Products. SmartSite™ Needle-free Valve. BAG ACCESS DEVICE. VENTED.	NA	9.5	0.5	NA	NA
MFX2309EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	160	190	19	3	4.1

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.

Further features:

BD Catalogue Number	Gravity Use	Pump Use	Vented Spike	Back Check Valve	Anti-Syphon Valve	Needle-Free Connector	Filter Size	Change Interval	Lipid Resistant
MFX2250EV	Yes	No	Yes	No	No	Yes (Luer Lock, SmartSite™ Valve)	NA	Replace every 72 hours or after 100 activations of Needle-free valve whichever occurs first. For infusions of blood, blood products or lipid emulsions replace every 24 hours.	Yes
MFX2309EV	Yes	No	Yes	No	No	Yes (SmartSite™ Valve)	15 µm		Yes

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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)
MFX2250EV	Name and Address: BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland ISO 13485 Certificate No.: MD71300	CE certified with BSI (2797) MDD Certificate No.: CE 506414 UKCA certified: N/A	Name and Address: CareFusion Italy 312 S.p.A. Unipersonale Via Giacomo Matteotti 27/A Villamarzana (RO) 45030, Italy ISO 13485 Certificate No.: MD 692496	Name and Address: EC Representative: Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
MFX2309EV			Name and Address: CareFusion BH 335 d.o.o Cazin Mihaljevac bb Cazin, 77220 Bosnia & Herzegovina ISO 13485 Certificate No.: MD 674365	

1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers 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	Component		Material
MFX2250EV	Luer Lock, SmartSite™ Valve	Body	Acrylic
		Female Luer	Polyurethane (PU)
		Piston	Silicon
	Spike*		Acrylonitrile butadiene styrene (ABS)
			Low-density polyethylene (LDPE)
			Acrylic copolymer
MFX2309EV	Rotating Luer Lock*		ABS
	Luer Lock Adapter		ABS
	Female Luer Lock		ABS
	Rotating Luer Lock Adapter		ABS
	Protective cap	Body	LDPE
		Filter	Acrylic copolymer
	SmartSite™ Valve*	Body	Acrylic
		Female Luer	Polyurethane (PU)
		Valve	Silicone
	SmartSite™ Valve triport and 2 valve without ring	Body	Polycarbonate
		Luer Lock	Polyurethane (PU)
		Valve	Silicone
	SmartSite™ Valve triport and 2 valve with ring	Body	Polycarbonate
		Luer Lock	Polyurethane (PU)
		Valve	Silicone
		Ring	Methylmethacrylate acrylonitrile butadiene styrene (MABS)
	Spike and cap*	Spike	ABS
		Cap	LDPE
		Membrane valve	Silicone
	Clamp		Polyoxymethylene (POM)
	Roller clamp		ABS (Acrylonitrile Butadiene Styrene)
	Filter		Polyamide (PA)
	Top Cap		ABS
	Ribbed drip chamber		Styrene-Butadienne (SB)
	Tube*		Polyurethane (PU)

* Indicates fluid path components that come into indirect contact with the human body.

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 25 March 2025, BD has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4),

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Material	Comment
	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.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 25 March 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)	**For BD Catalogue Number MFX2309EV:** Based on our ongoing data collection efforts and/or information received from our suppliers as per 25 March 2025, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the article and packaging with the product number as referenced above, in an individual concentration above 0.1% weight by weight (w/w). There is a polycarbonate component in this product. 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, 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. **For BD Catalogue Number MFX2250EV:** BD has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the article with the product number referenced above. It is not a building block of any of the raw materials utilized and is not intentionally added. BD has not done any testing to evaluate levels of this chemical in this product.
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.

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Material	Comment
	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 and packaging referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.
Heavy Metals in Packaging	Based on our ongoing data collection efforts and/or information received by our suppliers as per 25 March 2025, the products (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).
ROHS	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 scope of the EU RoHS Directive.
Heavy metals	Based on our ongoing data collection efforts and/or information received from our suppliers as of 25 March 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 (euMDR Annex I Sections 10.4.1a and 10.4.1b)	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 25 March 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.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 25 March 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 17 January 2023 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 products here referenced (MFX2250EV and MFX2309EV) are provided sterile and they are sterilized using Ethylene Oxide.
Single use clarification: MFX2250EV and MFX2309EV are placed on the market as sterile single use devices. Reuse constitutes misuse.

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1.11 Shelf life and storage conditions

The products' here referenced (MFX2250EV and MFX2309EV) shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
The shelf life of MFX2250EV and MFX2309EV will not exceed 3 years from date of packaging.
The product instructions for use indicate that the product is for single use only.
BD recommends to store in a dry and warm place, not exposed to strong light.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title
Harmonised 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 15986:2011	Symbol for use in the labelling of medical devices Requirements for labelling of medical devices containing phthalates.
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 10993-7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
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 device - Part 17: Establishment of allowable limits for leachable substances
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 11737-1:2018+A1:2021	Sterilization of medical devices - Microbiological methods Part 1: Determination of a population of microorganisms on product.
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.
BS EN ISO 15223-	Medical devices - Symbols to be used with medical device labels, labelling and

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1:2016/AC:2017	information to be supplied Part 1: General requirements.
BS EN 20594-1:1994	Conical fittings with a 6%(Luer) taper for syringes, needles and other certain medical equipment - part 1: General requirements
BS EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives - Application of risk management.
Non-Harmonised Standard Reference	
BS EN ISO 1135-4:2015/Corr 2016	Transfusion equipment for medical use. Transfusion sets for single use with pressure infusion apparatus.
BS EN ISO 1135-5:2015	Transfusion equipment for medical use. Transfusion sets for single use, gravity feed.
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 8536-5:2013	Infusion equipment for medical use - Part 5: Burette 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 8536-11:2015	Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment.
BS ISO 8536-12:2007 +A1:2013	Infusion equipment for medical use - Part 12: Check valves.
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 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
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.
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.
ISO 14001:2015*	Environmental Management System of the Manufacturing Site

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* The two (2) Manufacturing Sites are fully compliant with ISO 14001:2015:
  - CareFusion Italy, 312 S.p.A. Unipersonale Via Giacomo Matteotti 27/A, Villamarzana (RO) 45030, Italy
  - CareFusion BH 335 d.o.o Cazin, Mihaljevac bb Cazin, 77220, Bosnia & Herzegovina

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

1.13 Classification

MFX2250EV and MFX2309EV are EC Product Class I Sterile in accordance with Council Directive 93/42/EEC, Annex IX, Rule 2.

1.14 Medical Device Nomenclature

SKU	GMDN Code	GMDN Term
MFX2250EV	43324	Fluid transfer set, general-purpose
MFX2309EV	58977	Basic intravenous administration 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:

RoHS2 Directive	2011/65/EU	Infusion administration sets for gravity are not electrical or electronic equipment.
Radio Equipment Directive	2014/53/EU	Infusion administration sets for gravity are not electrical or electronic equipment and cannot intentionally emit and/or receive radio waves.

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Low Voltage Directive	2006-95-EC	Infusion administration sets for gravity are out of scope of the Low Voltage Directive according to Annex II of 2014/35/EU, which lists "Electrical equipment for radiology & medical purposes"
Waste electrical and electronic Equipment (WEEE)	2002/96/EC	Infusion administration sets for gravity are not electronic equipment and do not create electrical waste.
Battery	2006/66/EC	Infusion administration sets for gravity do not use batteries.
EMC Directive	2014/30/EU	Infusion administration sets for gravity are not operated by electrical energy source such as electricity / battery and therefore fall outside the scope of this directive.
Machinery Directive	2006/42/EC	Infusion administration sets for gravity do not include Machinery.

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*
MFX2250EV	Alaris™ Products. SmartSite™ Needle-free Valve. BAG ACCESS DEVICE. VENTED.	1	50	100	Yes
MFX2309EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	1	20	40	Yes

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

2.2 Packaging materials

BD Catalogue Number	Component	Material
MFX2250EV	Top Web	Medical Paper
	Bottom Web	100 µm Plastic Polyester Film
	Shelf Container	LDPE
	Export Container	Cardboard
MFX2309EV	Top Web	Medical Paper
	Bottom Web	PP (Polypropylene)/ PA (Polyamide) /PE (Polyethylene) Coextruded Film
	Shelf Container	High-density polyethylene (HDPE)
	Export Container	Cardboard

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.

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-Recycled Content:

BD Catalogue Number	Packaging Type	Packaging Recycled content	Recyclability
MFX2250EV, MFX2309EV	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

2.4 Examples of labelling

Pouch label extracted from document BDLD00116 Revision 02 version B related to reference MFX2250EV:



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Shipper Box label extracted from document MFX2250EV Revision 04 version D related to reference MFX2250EV:



Symbols insert extracted from document BDLD00154 Revision 06 version F related to reference MFX2250EV (page 01 of 02):

	en	bg	cs	da	de	el	es	et	fi	fr	hr	hu	it	lt
	WARNING: Reuse compromises safety and efficacy.	ПРЕДУПРЕЖДЕНИЕ: Повторната употреба излага на риск безопасността и ефикасността.	VAROVÁNÍ: Opětovné použití snižuje bezpečnost a účinnost.	ADVARSEL: Genbrug går ud over sikkerheden og anvendelsen.	WARNUNG: Durch Wiederverwendung wird die Sicherheit und Wirksamkeit beeinträchtigt.	ΠΡΟΕΙΔΟΠΟΙΗΣΗ: Η επαναχρησιμοποίηση εις βάρος την ασφάλεια και λειτουργικότητα.	ADVERTENCIA: La reutilización compromete la seguridad y eficacia.	TÄHELEPANU: Taaskasutamine ei ole lubatud.	VAROITUS: Uudelleenkäyttö vaikuttaa vaikutuksykykyyn ja vaarantaa turvallisuuden.	PRECAUTION: La réutilisation compromet la sécurité et l'efficacité.	UPOZORENJE: Ponovno korištenje dovodi u pitanje sigurnost i učinkovitost.	FIGYELMEZTETÉS: Az újrefelhasználás veszélyezteti a biztonságot és a hatékonyságot.	AVVERTENZE: Il riutilizzo compromette l'efficacie e la sicurezza.	ĮSPĖJIMAS: Pakartotinis naudojimas neigiamai įtakoja saugumą ir efektyvumą.
PHT DEHP	Contains DEHP, a phthalate potentially hazardous in the prolonged treatment of children or pregnent 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 fatal som anses for at være skadeligt ved langvarige behandlinger af børn samt gravide eller ammende kvinder. Det er op til det medicinske personale at vægte fordelene ved brugen af dette produkt mod 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 επικίνδυνο κατά την παρατεταμένη αγωγή παιδιών ή εγκύων ή γυναικών σε θηλασμό. Οι θεμτπούντες ιατροί πρέπει να εξισορροπούν τα οφέλη της χρήσης αυτού του προϊόντος έναντι των προβλεπτμων 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-ftaalia, joka voi olla vaarallista pitkäaikaisessa käytössä lasten ja raskaana olevien tai imettävien naisten hoidossa. Hoitohenkilökunnan tulee arvioida, ovatko 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 bienfaits de l'utilisation de ce produit avec les risques prévisibles.	Sadrži DEHP, ftalat koji prilikom dugog korištenja može predstavljati potencijalnu opasnost za djecu, trudnice ili dojilje. Medicinsko osoblje mora odvagnuti između koristi od korištenja ovog proizvoda i predvidljivih rizika.	A termék DEHP-t, vagyis egy olyan ftalátot tartalmaz, amely veszélyes lehet gyermekek, terhes nők, illetve szoptató anyák tartós kezelésekor. Az orvosnak mérlegelnie kell a használat előnyeit az előreláthato kockázatokkal szemben.	Contiene DEHP, uno ftalato potenzialmente pericoloso in caso di trattamento prolungato su bambini o donne in stato di gravidanza o allattamento. I medici devono valutare i vantaggi derivanti dall'utilizzo di questo prodotto, confrontandoli con i rischi prevedibili.	Sudėtyje yra ftalato DEHP, kuris gali kilti pavojingas ilgai gydant vaikus, nėščias ar žindančias motinis. 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.	Non-pyrogenic.	Непирогенен.	Nepyrogenní.	Pyrogenfri.	Pyrogenfrei.	Μη πυρετογόνο.	Apirógeno	Mittepürogeenne.	Pyrogeenitön.	Apyrogènes.	Nije pirogeno.	Nem gyűlékony.	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 gået i stykker.	Nicht verwenden wenn Verpackung beschädigt ist.	Μην χρησιμοποιείτε εάν το πακέτο είναι κατεστραμμένο.	No usar si el envase está dañado.	Ära kasuta kahjustatud 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.	Da 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.	ΝΝ ΣΤΑΓΟΝΕΣ ΑΝΑ ML.	NN GOTAS POR ML.	TILKADE ARV ÜHES ML-S	NN GTT/ML.	NN GOUTTES PAR ML.	NN KAPI PO ml.	NN CSEPP ML-ENKÉNT	NN GOCCE PER ML.	LAŠŲ SKAIČIUS MILLITRE
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 Ivac™ 560/570/590 Pump	ISO8536-8—IS—P													

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Symbols insert extracted from document BDLD00154 Revision 06 version F related to reference MFX2250EV (page 02 of 02):

	lv	nl	no	pl	pt	ro	ru	sk	sl	sr	sv	tr	ja	zh
	BRĪDINĀJUMS: Atkārtota izmantošana apdraud drošību un efektivitāti.	WAARSCHUWING: Hergebruik beïnloed doeltreffendheid.	ADVARSEL: Gjenbruk kompromitterer sikkerhet og effekt.	OSTRZEŻENIE: Ponowne użycie stanowi kompromis pomiędzy bezpieczeństwem a wydajnością.	AVISO: Reutilizar compromete eficácia e segurança.	ATENTIE: Reutilizarea periclitează siguranța și eficacitatea.	ПРЕДУПРЕЖДЕНИЕ: Повторное использование снижает уровень безопасности и эффективности.	VAROVANIE: Opakované použitie znižuje bezpečnosť a účinnosť.	SVARILO: Ponovna uporaba ogroži varnost in učinkovitost.	UPOZORENJE: Ponovno 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 ilgstoši ārstēšanām bērniem, grūtniecēm un ar krūti barojošām mātēm. Medijiem ir jāzvērē, vai preparāta izmantošana atļaisno iespējamo apdraudējumu.	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.	Zawiere DEHP, ftalan, który może być niebezpieczny przy dłuższym 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 ДЭГФ, фталат, 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 nákový 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 dolgotrajnem 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 voditi računa o balansu između prednosti korišćenje ovog proizvoda i predvidivih opasnosti.	Innehåller DEHP, en ftalat som är potentiellt skadlig vid långtidsbehandling av barn och gravida eller ammande kvinnor. Medicinskt ansvariga måste balansera nyttan av användning av produkten mot den överskådliga risken.	Uzun süre tedavi gören çocuklar ile hamile ve emziren kadınlarda potansiyel olarak tehlikeli bir ftalat olan DEHP içerir. Bu nedenle, ürünün kullanımındaki 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 FLALÁTOV	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 LATEKSA	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 pirogēns.	Pyrogeen vrij.	Ikke-pyrogen.	Wolne od pirogenów.	Apirogénico.	Apirogen.	непироге́нный.	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 используйте, если упаковка повреждена.	Nepoužívajte, pokiaľ je obal poškodený.	Ne uporabljajte v primeru poškodovanega paketa.	Ne koristite ako je pakovanje oštećeno.	Använd inte om förpackningen är skadad.	Paket aşılmış 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。
nn ml	PILIENI ML.	NN DRUPPELS PER ML.	NN DRÅPER PR ML.	LICZBA 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
xx µm	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	ISO8536-8—IS—P													

Alaris™ CC/GP/GW/SE/VP Pump

Ivac™ 560/570/590 Pump

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

IFU insert (English part only) extracted from document BDLD00157 Revision 02 version B related to reference MFX2250EV:

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

Alaris™ Products

SmartSite™ Needle-free Valve

(bg) Безиглен клапан SmartSite™
(cs) SmartSite™ Ventil bez jehly
(da) SmartSite™ Nålefri Ventil
(de) SmartSite™ Nadelfreies Ventil
(el) Βαλβίδα SmartSite™ χωρίς βελόνα
(es) Válvula Sin Aguja SmartSite™
(et) SmartSite™ nõelavaba klapp
(fi) SmartSite™ Neulaton Venttiili
(fr) Valve Sans Aiguille SmartSite™
(hr) Bezigleni pripoj SmartSite™
(hu) SmartSite™ tű nélküli szelep
(it) Valvola SmartSite™ Senza Ago
(lt) SmartSite™ beadatinis vožtuvas
(lv) SmartSite™ bez adatas vārsts
(nl) SmartSite™ Naaldloze Klep
(no) SmartSite™ Nålefri ventil
(pl) Zawór bezigłowy SmartSite™
(pt) Valvula Sem Agulha SmartSite™
(ro) Supapă fără ac SmartSite™
(ru) Безыгольчатый клапан SmartSite™
(sk) Bezihlový ventil SmartSite™
(sl) SmartSite™ brezigelni ventil
(sr) SmartSite™ bezigleni ventil
(sv) SmartSite™ Nålfri Ventil
(tr) SmartSite™ İğnesiz Valf
(ja) SmartSite™ 無針バルブ
(zh) SmartSite™ 无针阀

CE 2797 STERILE EO

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

BD

(en) Addendum to Administration Set Directions for Use

Precautions:
- If Needle-free valve is accessed by a needle in an emergency the valve will be damaged causing leakage. Replace Needle-free valve immediately.
- Needle-free Valve contraindicated for blunt cannula systems
- DO NOT leave slip luer syringes unattended.

DIRECTIONS - Use Aseptic Technique

1. Prior to every access, swab top of Needle-free valve port with 70% isopropyl alcohol (1-2 seconds) and allow to dry (approximately 30 seconds).
   NOTE: Dry time is dependent on temperature, humidity, ventilation of the area.
2. Prime valve port.
   NOTE: If applicable, attach syringe to Needle-free valve port and aspirate miniscule air bubbles.
   NOTE: If the syringe has a slip luer, the syringe should be inserted and then rotated a ¼ turn. Engagement should be confirmed by the user. Inadvertent disconnection may lead to a leakage from the syringe. For critical applications, e.g. oncology, a luer lock syringe should be used with the SmartSite needle free device.
3. Attach male luer of valve port to female luer of connecting device.
4. Replace every 72 hours or after 100 activations of Needle-free valve which ever occurs first. For infusions of blood, blood products or lipid emulsions replace every 24 hours.
   NOTE: During use of Needle-free valve port, fluid may be observed between the housing and blue piston. This fluid does not enter the fluid path and requires no action.
   NOTE: For product questions or Needle-free valve educational materials contact your BD representative. The Center for Disease Control, Infusion Nurses Society (USA) and other organizations publish guidelines useful in developing facility guidelines. Consult facility protocols.

REVISION	CHANGE SUMMARY
01	Initial release according to new template, CO # 20450
02	- Initial release according to TDS EMEA-SOP039-F1 based on Technical Documentation STED200 Rev.82/Ver.J – March 2025 - Removal of BD Catalogue Numbers MFX2310EV and MRX2311EV - Addition of BD Catalogue Number MFX2250EV

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