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 system. Secondary Set. Oncology.
Sterile, Single-use

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

Product codes: MFX2301EV, MFX2302EV, MFX2304EV

TDS number: V201-203 Rev. 02
Veeva Vault number: BD-154822
August-2025

1. General Information

1.1 Intended purpose

The intended use of the gravity administration 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

Alaris™ Products. SmartSite™ Needle-free system. Secondary Set is CE certified under Medical Device Directive (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 Alaris™ Products. SmartSite™ Needle-free system. Secondary Sets are comprised of elastic tubing made of PU (Polyurethane) with pinch clamps.
Both sides of the administration sets are ending with Male Luer Lock and priming cap (protecting cap with hydrophobic filter) at the distal end. Additionally, one side is provided with back check valve. The set contains also: a needle-free injection port - SmartSite™.



Figure 1: MFX2301EV



Figure 2: MFX2302EV

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Figure 3: MFX2304EV

BD Catalogue Number	MFX2301EV	MFX2302EV	MFX2304EV
BD Product Description	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Vented. Back Check Valve. Prime with non-hazardous fluid.	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Vented. Back Check Valve. 0.2 µm Filter. Prime with non-hazardous fluid.	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Male To Male. Back Check Valve. Prime with non-hazardous fluid.
Tube Length (cm)	31	43	31
Total Set Length (cm)	38	55	40
Priming Volume (mL)	3	6	3
Tube internal diameter (mm)	3	3	3
Tube outer diameter (mm)	4.1	4.1	4.1
Macrobore / Microbore	Macrobore	Macrobore	Macrobore
Luer Lock	Fixed	Fixed	Rotating
Back Check Valve	Yes	Yes	Yes
SmartSite™	Yes (1)	Yes (1)	Yes (1)
Pressure Resistance (bar)	2	2	2
Filter Size (µm)	N/A	0.2	N/A
Lipid Resistant	Yes	Yes	Yes
Change Interval	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.	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.	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.

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)
MFX2301EV MFX2302EV MFX2304EV	Name and Address: BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Bâtiment A4, Eysins, CH-1262 Switzerland ISO 13485 Certificate No.: MD71300	CE certified with BSI (2797) MDD Certificate No.: CE 506414 UKCA certified: N/A	Name and Address: CareFusion BH 335 d.o.o Cazin, Mihaljevac bb, Cazin, 77220, Bosnia & Herzegovina. ISO 13485 Certificate No.: MD 674365	Name and Address: EC Representative: Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland

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.

1.6 Materials

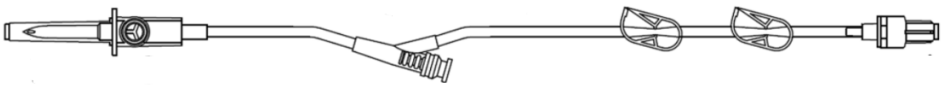


Figure 4: MFX2301EV

BD Catalogue Number	Component		Material
MFX2301EV	Protective Cap		LDPE (Low-Density Polyethylene), acrylic copolymer on nylon support
	SmartSite™ valve	Body	Acrylic
		Top Cap	PU (Polyurethane)
		Needle-Free Valve	Silicone Rubber
	Spike		ABS (Acrylonitrile-Butadiene-Styrene)
	Cap		LDPE
	Membrane		Silicone
	Pinch Clamp		POM (Polyoxymethylene)
	Luer Lock with Back Check Valve	Body	MABS (Methyl methacrylate acrylonitrile butadiene styrene)
		Membrane	Silicone
	Tube		PU

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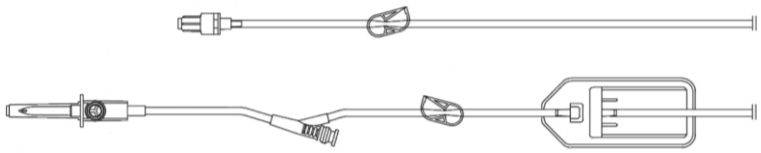


Figure 5: MFX2302EV

BD Catalogue Number	Component		Material
MFX2302EV	Protective Cap		LDPE, acrylic copolymer on nylon support
	SmartSite™ valve	Body	Acrylic
		Top Cap	PU (Polyurethane)
		Needle-Free Valve	Silicone Rubber
	Spike		ABS
	Cap		LDPE
	Membrane		Silicone
	Pinch Clamp		POM
	Luer Lock with Back Check Valve	Body	MABS
		Membrane	Silicone
	In-Line Filter Housing		Acrylic
	Filter 0.2µm		PES (Hydrophilic Polyethersulfone)
	Tube		PU

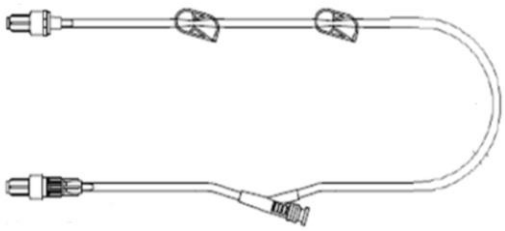


Figure 6: MFX2304EV

BD Catalogue Number	Component		Material
MFX2304EV	Rotating Male Luer Lock		ABS (Acrylonitrile-Butadiene-Styrene)
	Protective Cap		LDPE, acrylic copolymer on nylon support
	SmartSite™ valve	Body	Acrylic
		Top Cap	PU (Polyurethane)
		Needle-Free Valve	Silicone Rubber
	Pinch Clamp		POM
	Back Check Valve	Body	MABS
		Membrane	Silicone
	Tube		PU

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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 10 July 2025, BD has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzenedicarboxylic 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), Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7), Di-n-octyl phthalate (DNOP) (CAS# 117-84-0), Diisononylphthalate (DINP) (CAS# 28553-12-0), or Diisodecylphthalate (DIDP) (CAS# 26761-40-0, 68515-49-1) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% w/w.
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 10 July 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)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 July 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% (w/w).
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 devices (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, and EU No 722/2012).

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Material	Comment
Polyvinyl chloride (PVC)	The medical devices referenced above have been designed and manufactured with PVC in the tubing components.
RoHS directive, heavy metals and 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 10 July 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 July 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 10 June 2022 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

Sterilization Method: Ethylene Oxide Sterilization

1.11 Shelf life and storage conditions

The Alaris™ Products. SmartSite™ Needle-free system. Secondary Set shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
All BD Catalogue Numbers referenced in this document have a shelf life of **3 years**. 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.

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Standard reference number	Title
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 devices - 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 15223-1:2016/AC:2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.
BS EN 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.
ISO 14001:2015	Environmental Management System
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.

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Standard reference number	Title
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.

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

1.13 Classification

All BD Catalogue Numbers in this document are Medical Device Class I Sterile in accordance with Council Directive 93/42/EEC, Annex IX, Rule 2.

1.14 Medical Device Nomenclature

GMDN Code: 58977
GMDN Term: 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.

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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.
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 and 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*
MFX2301EV	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Vented. Back Check Valve. Prime with non-hazardous fluid.	1	25	50	Yes
MFX2302EV	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Vented. Back Check Valve. 0.2 µm Filter. Prime with non-hazardous fluid.	1	25	50	Yes
MFX2304EV	Alaris™ Products. SmartSite™ Needle-free System. Secondary Set. Oncology. Male To Male. Back Check Valve. Prime with non-hazardous fluid.	1	25	50	Yes

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

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2.2 Packaging materials

BD Catalogue Number	Component	Material
MFX2301EV	Unit Pack	Top Web: 60gsm Medical Paper
		Bottom Web: 80µm PP (Polypropylene)/PA (Polyamide)/PE (Polyethylene) Coextruded Film
	Shelf Box	Polyethylene bag
	Shipping Case	Cardboard export container
MFX2302EV, MFX2304EV	Unit pack	Top Web: medical paper model sterikraft G 60g/m^2
		Bottom Web: Laminated Multi-layered plastic
	Shelf Box	Polyethylene bag
	Shipping Case	Cardboard export container

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:

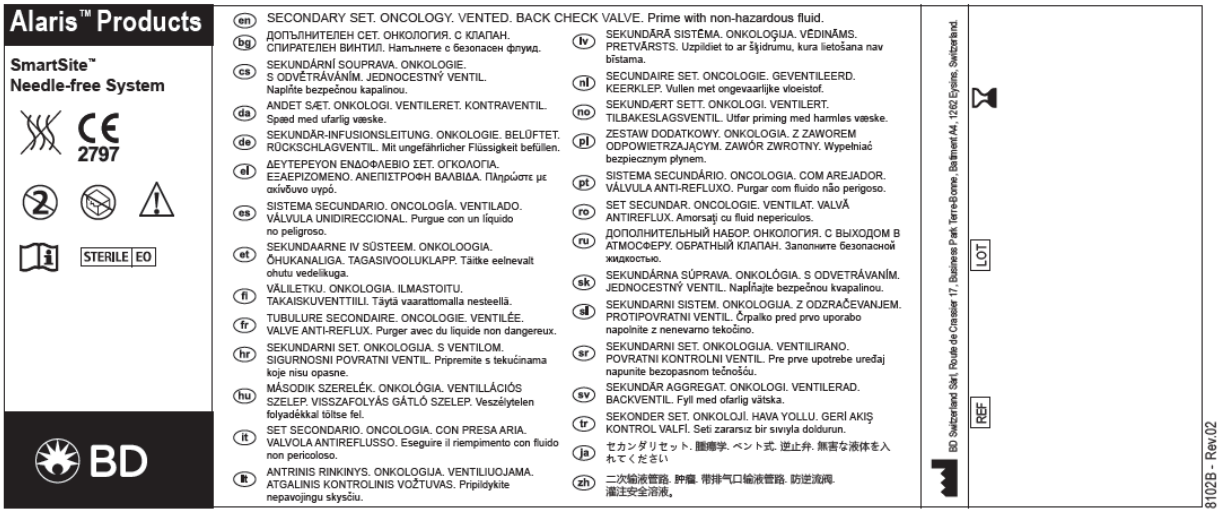
BD Catalogue Number	Packaging Type		Recycled Content	Recyclability
MFX2301EV MFX2302EV MFX2304EV	Primary Packaging: Multilayer laminate plastic and paper		0%	Two materials – designed to be peeled apart.
				Paper is recyclable
				Multilayer laminate is recyclable through monomer recovery recycling methods
	Secondary Packaging: Plastic Bag		Unknown	HDPE is recyclable
	Tertiary Packaging	Outer Packaging: Corrugated box	Unknown	Corrugated box is recyclable.
		Label and IFU: Paper		Paper is recyclable.
		Clapboard: Corrugated kraft		The corrugated kraft is recyclable.
		Pallet: Wooden		The wooden is recyclable.
		Corner stripe: Corrugated kraft		The corrugated kraft is recyclable.

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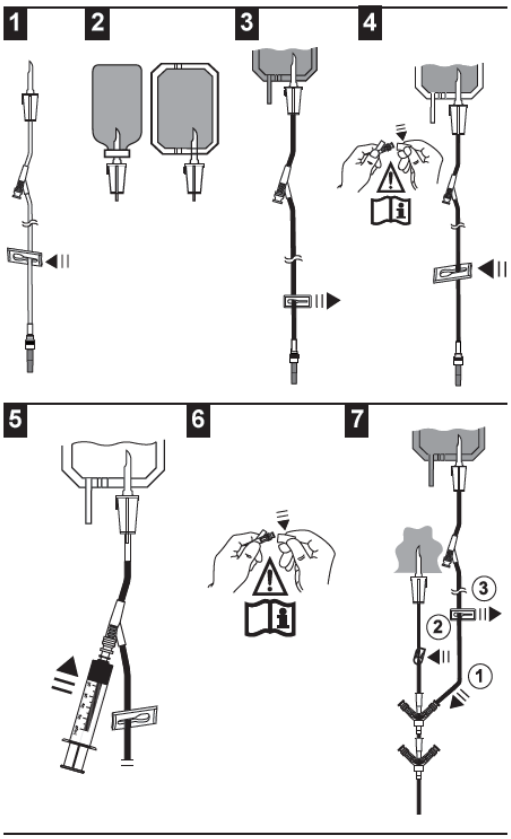
2.4 Examples of labelling

Primary Packaging (Top Web) extracted from document BDLD00118 Revision 02 / Version B related to reference MFX2301EV:



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en - DEHP or Natural Rubber Latex are not part of the material formulation. **bg** - DEHP или естественият каучуков латекс не са част от състава на материала. **cs** - Materiál přípravku neobsahuje DEHP nebo přírodní latex. **da** - Produktet er ikke fremstillet af DEHP eller naturlig gummilatex. **de** - Die Materialformulierung ist frei von DEHP und Naturkautschuklatex. **el** - Το DEHP ή το φυσικό ελαστικό latex δεν αποτελούν μέρος της κατασκευής υλικού. **es** - La formulación del material no contiene DEHP ni látex de caucho natural. **et** - Materjali koostises ei ole DEHP-i ega looduslikku kummilateksit. **fi** - Materiaalit eivät sisällä DEHP:tä tai luonnonkumia (lateksia). **fr** - La formulation du matériau ne contient pas de DEHP ni de latex de caoutchouc naturel. **hr** - Formula materijala ne sadrži DEHP niti prirodnu gumu. **hu** - Az anyagösszetevők nem tartalmaznak DEHP-t vagy természetes gumilatexet. **it** - Il materiale non contiene DEHP o lattice di gomma naturale. **lt** - DEHP arba natūralus kaučiuko lateksas nėra medžiagos sudėtinės dalys. **lv** - Materiāla sastāvā nav DEHP vai dabiskā kaučuka lateksa sastāvdaļu. **nl** - De materiaalsamenstelling bevat geen DEHP of natuurrubberlatex. **no** - DEHP eller naturgummilateks er ikke en del av materialblandingen. **pl** - DEHP i lateks naturalny nie wchodzą w skład żadnego z materiałów. **pt** - DEHP ou látex de borracha natural não estão presentes no material. **ro** - DEHP sau latexul de cauciuc natural nu face parte din compoziția materialului. **ru** - ДЭГФ и натуральный каучуковый латекс не входят в состав материала. **sk** - DEHP ani prírodný latex nie sú súčasťou zloženia materiálu. **sl** - Ni izdelano iz DEHP in lateksa iz naravne gume. **sr** - Ne sadrži DEHP i prirodnu gumu. **sv** - Materialet innehåller inte DEHP eller naturgummi. **tr** - DEHP veya Doğal Kauçuk Lateks, malzeme formülasyonunun parçaları değildir. **ja** - DEHP および天然ゴムラテックスは材料に使用されていません。 **zh** - 材料配方不含 DEHP 或天然乳胶。

8102B - Rev.02

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Shipper Box label extracted from document MFX2301EV Revision 02 / Version B related to reference MFX2301EV:



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IFU insert (English part only) extracted from document BDLD00157 Revision 02 / Version B related to reference MFX2301EV:
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.

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

REVISION	CHANGE SUMMARY
01	TDS released in May 2017
02	August 2025: - Second release according to TDS template EMEA-SOP039-F1 Rev.02 based on Technical Documentation STED File 200 Rev. 82 / Ver. J – March 2025 - Addition of BD Catalogue Numbers MFX2301EV and MFX2302EV. - Updated section 1.1 Intended purpose, 1.2 Intended User and 1.3 General Medical Devices description as per the latest technical documentation. - Update of section 1.4 certification. - Added section 1.5 UDI-DI and Basic UDI-DI. - Update of section 1.6 materials. - Update of the statements of section 1.7 Materials of concern. - Updated statement of section 1.8 REACH information. - Update of section 1.12 applied standards, few standards were added as per latest release STED. - Update of section 1.14 Medical Device Nomenclature, GMDN number and term updated as per latest STED. - Update of section 1.16 Other Information, updated as per latest TDS template. - Updated section 2.1 Packaging configuration. - Updated section 2.2 Packaging material. - Update of recyclability information from section 2.3 Recycled material in packaging. - Update of section 2.4, label pictures are updated with latest released labels.

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