BD Plastipak™ syringes without needles Sterile

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

Number: V201-009 – Rev. 03
2020 - September

1. General Information

1.1 Intended use

The three-piece BD Plastipak™ syringes are medical devices used for injection of medicinal substances, blood extraction, and aspiration of fluids from vials, ampoules and parts of body below the surface of the skin.

1.2 General description

The syringe assembly consists of a plastic barrel imprinted with a graduated scale. The inner surface of the barrel is lubricated with silicone oil, and a rubber piston attached to a plastic plunger rod is assembled into the barrel.

The syringe is then packaged into a blister pack which is hermetically sealed and serves as tamper evidence. The blister packages are then packaged into shelf packs and shrink-wrapped into bundles for shipped/transport.

BD Catalog Number	BD Product Description	Capacity	Scale Graduation
303174	SYRINGE 1ML LS U100 SP120	1 mL	International Units
303173	SYRINGE 1ML LS U40 SP120	1 mL	International Units
303172	SYRINGE 1ML LS SP120	1 mL	0.01 mL
301183	SYRINGE 20ML LS 60/PKG	20 mL	1 mL
300613	SYRINGE 20ML E/T	20 mL	1 mL
301231	SYRINGE 30ML LS	30 mL	1 mL
300866	SYRINGE 60ML E/T	50/60 mL	1 mL
300867	SYRINGE 50ML CT	50/60 mL	1 mL
300605	SYRINGE 100ML CATH TIP	100 mL	2 mL
309654	SYRINGE 60ML S/T LATEX FREE CONFIGURE	60 mL	1 mL
301189	SYRINGE 20ML LL 60/PKG	20 mL	1 mL
300629	SYRINGE 20ML LL 120/PKG	20 mL	1 mL
302830	SYRINGE 20ML LL S/C 48	20 mL	1 mL
301229	SYRINGE 30ML LL	30 mL	1 mL
300865	SYRINGE 50ML LL	50/60 mL	1 mL
309653	Syringe 60ML LL Tip 1ML	60 mL	1 mL
309628	SYRINGE 1ML LL	1 mL	0.01 mL
309658	SYRINGE 3ML LL EURO 200 S/C	3 mL	0.1 mL
309649	Syringe 5ML LL Euro 125 S/C	5 mL	0.2 mL
300912	SYRINGE 10ML LL EUROGRAPHICS	10 mL	0.2 mL
305959	SYRINGE 10ML LL	10 mL	0.2 mL
300869	SYRINGE 50ML LL AMBER	50/60 mL	1 mL
302832	SYRINGE 30ML LL S/C 56	30 mL	1 mL
302146	SYRINGE 10ML E/T	10 mL	0.2 mL
302236	SYRINGE 5ML LS W/RED PLUNGER	5 mL	0.2 mL
309620	CATHETER TIP SYRINGE	50mL	1mL

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

Further features:

N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
305959 301189* 300629* 301229* 300865* 300869*	**Address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín de Guadalix (Madrid) Spain **ISO 13485** Certificate N° 2012 07 0013 EN	CE certified with AEMPS (0318) Certificate N°95 06 0005 CP	**Address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín de Guadalix (Madrid) Spain **ISO 13485** Certificate N° 2012 07 0013 EN	N/A
303174 303173 303172 300866* 301231* 300613* 301183* 300867* 300605*		CE certified with AEMPS (0318) Certificate N°2000 06 0273 CP		
302830 302832 309654 309653 309620	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA **ISO 13485** Certificate N° MD19.2305	CE certified with NSAI (0050) Certificate N°252.231	**Address:** BD Medical Surgical Systems 2153 12th Avenue Columbus, NE 68601, USA **ISO 13485** Certificate N°MD19.2143	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse, Belgium
309628 309658 309649 300912			**Address:** Becton, Dickinson and Company Route 7 & Grace Way Canaan, CN 06018, USA **ISO 13485** Certificate N° MD19.2369	
302146 302236	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore **ISO 13485** Certificate N° MD 81426	CE certified with BSI (2797) Certificate N° CE 01487	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore **ISO 13485** Certificate N° MD 81426	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse, Belgium

* Ongoing project: BD is transferring the legal manufacturer from BD Drogheda (Ireland) to BD San Agustin (Spain) and from Notified Body NSAI (Ireland) to AEMPS (Spain), completion date in 2020.

There will be no renewal of CE certificate 252.156 (NSAI 0050) from Drogheda as products are currently transitioning to the CE certificate number 95 06 0005 CP or 2000 06 0273 CP (AEMPS 0318) (as per above table). There is no change to form, fit or function. Changes are limited to legal manufacturer name and address and notified body. Each label will be updated at different times.

The first lot for each SKU with new legal manufacturer and notified body number is:

- 301189 – 1st Lot number 1912285
- 300629 – 1st Lot number 1910710
- 301229 – 1st Lot number 1910721
- 300865 – 1st Lot number 1909704
- 300869 – 1st Lot number 1910725
- 300866 – 1st Lot number 1911287
- 301231 – 1st Lot number 1911208
- 300613 – 1st Lot number 1910270
- 301183 – 1st Lot number 1911242
- 300867 – 1st Lot number 1912224
- 300605 – 1st Lot number 2002501

1.4 Materials

Component	Material
Barrels	Polypropylene
Plunger rods	Polypropylene
Barrels for BD catalog number 309628	Polycarbonate
Stoppers	Latex free elastomer
Lubricant	Medical grade silicone oil, <0.25mg/cm^2
Scale	Ink + dissolvent

BD Plastipak™ Amber syringes, such as 300139 and 300869, have the barrel colored to reduce U.V. light for administration of light sensitive medications. The light transmission has been characterized as per the transparency test (method 1) as described in the Japanese Pharmacopeia XVI.
According to such method the light transmissibility (%) is characterized under a UV light source emitting at 450nm. The light transmission is 5.6± 0.2% (mean ± standard deviation) according to the transparency test.

1.5 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 14 April 2020, BD has not identified any • 1,2-Benzendicarboxylic 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), • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis(2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • N-pentyl-isopentylphthalate (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% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 14 April 2020, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 14 April 2020, 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). 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 these products.
Bisphenol A for BD reference 309628	Based on our ongoing data collection efforts and/or information received from our suppliers as per 14 April 2020, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles 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 and BD test results, 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.
Substances of animal origin BSE/TSE	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 acids 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

Material	Comment
	Annex C.5 of EN ISO 22442-1:2015 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, as recognized by MEDDEV 2.4/1, 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 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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 14 April 2020, 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 15 January 2019 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 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.

1.8 Sterilization method

- **Ethylene Oxide Sterilization** following *EN ISO 11135-1*. 301183, 301189, 300867, 300605, 303172, 303173, 303174, 305959, 300629, 301229, 300865, 300866, 300869, 301231, 300613, 302146, 302236. EO residues are within applicable regulation.

- **Radiation Sterilization** following EN ISO 11137-1 References sterilized with radiation: 309628, 309658, 309649, 300912, 302830, 302832, 309653, 309654 and 309620.

1.9 Shelf life and storage conditions

The BD Plastipak™ Syringes shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
All BD Plastipak™ Syringes have a shelf life of 5 years except BD Plastipak™ Syringe reference 300605 has a shelf life of 18 months.

Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity for products with Becton Dickinson S.A., Camino de Valdeoliva s/n, 28750-San Agustín del Guadalix, Spain as Legal Manufacturer (minor differences may exist between different Legal Manufacturer):

Harmonized Standards	
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
EN 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
EN 20594-1:1993 /A1:1997/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN ISO 10993 series	Biological evaluation of medical devices
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
Non-Harmonized Standards	
EN 1041:2008 /A1:2013	Information supplied by the manufacturer of medical devices
ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
UNE-EN ISO 11135:2015	Sterilization of health-care products --. Ethylene oxide
EN ISO 11138-2:2017	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment –Part 2: Lock Fittings
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices - Part 1: 2009 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: 2006 Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods - Part 1:2006/AC:2009 Determination of a population of microorganisms on products
ISO 14971:2019	Medical devices. Application of risk management to medical devices

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

1.11 Classification

- **Class I:** 303172, 303173, 303174, 300866, 301231, 300613, 301183, 300867 and 300605, Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.
- **Class I**: 309628, 309658, 309649, 300912, 309653, 309654, 302830, 302146 and 302236 Rule 1, Annex IX, Section III of the Medical Device Directive 93\42\EEC as amended.
- **Class IIa**: 301189, 300629, 301229 300865, 300869, 305959 and 309620, Rule 2, Annex IX of the Medical Devices Directive 93/42/EEC as amended.

BD project of legal manufacturer transfer from BD Drogheda (Ireland) to BD San Agustin (Spain) and from Notified Body NSAI (Ireland) to AEMPS (Spain).

Consequently, BD catalogue number 300866, 301231, 300613, 301183, 300867 and 300605 were initially classified as **class IIa** under Ireland and are now classified as **class I** with a measuring function under Spain.

In addition, BD catalogue number 305959 was initially classified as **class I** and is now classified as **class IIa**, without changing legal manufacturer (Spain) but change from CE mark number 2000 06 0273 CP to CE mark number 95 06 0005 CP.

Then, BD catalogue number 302146 and 302236 were initially classified as **class IIa** and are now classified as **class I** with a measuring function, without changing legal manufacturer (Singapore) or CE marking certification.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Plastipak™ Syringes are referenced as follows:

GMDN code and Term	References
GMDN Code: 47017 GMDN Term: General-purpose syringe, single use	301183, 301189, 300867, 300605, 302830, 302832, 309628, 309649, 309653, 309654, 309658, 300912, 303172, 305959, 303173, 303174, 300629, 301229, 300865, 300866, 300869, 301231, 300613, 309620.
GMDN Code: 35904 GMDN Term: Injection syringe, Metered-delivery hypodermic syringe, single use	302146, 302236.

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the 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.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact *(Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs")* is not required as 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 FDA Pharmaceutical is not applicable for Medical Devices.
- EU legislation restricting the use of hazardous substances in electrical and electronic equipment (RoHS Directive 2002/95/EC) is not applicable to these medical devices

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
303174	SYRINGE 1ML LS U100 SP120	1	120	960	No
303173	SYRINGE 1ML LS U40 SP120	1	120	960	No
303172	SYRINGE 1ML LS SP120	1	120	960	No
301183	SYRINGE 20ML LS 60/PKG	1	60	240	No
300613	SYRINGE 20ML E/T	1	120	480	No
301231	SYRINGE 30ML LS	1	60	240	No
300866	SYRINGE 60ML E/T	1	60	240	No
300867	SYRINGE 50ML CT	1	60	240	No
300605	SYRINGE 100ML CATH TIP	1	50	100	No
309654	SYRINGE 60ML S/T LATEX FREE CONFIGURE	1	40	160	No
301189	SYRINGE 20ML LL 60/PKG	1	60	480	No
300629	SYRINGE 20ML LL 120/PKG	1	120	480	No
302830	SYRINGE 20ML LL S/C 48	1	40	160	No
301229	SYRINGE 30ML LL	1	60	240	No
300865	SYRINGE 50ML LL	1	60	240	No
309653	Syringe 60ML LL Tip 1ML	1	40	160	No
309628	SYRINGE 1ML LL	1	100	800	Yes
309658	SYRINGE 3ML LL EURO 200 S/C	1	100	800	Yes
309649	SYRINGE 5ML LL Euro 125 S/C	1	100	400	Yes
309620	CATHETER TIP SYRINGE	1	40	160	No
300912	SYRINGE 10ML LL EUROGRAPHICS	1	100	400	Yes
305959	SYRINGE 10ML LL	1	100	400	No
300869	SYRINGE 50ML LL AMBER	1	60	240	No
302832	SYRINGE 30ML LL S/C 56	1	56	224	No
302146	SYRINGE 10ML E/T	1	100	400	No
302236	SYRINGE 5ML LS W/RED PLUNGER	1	100	400	No

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

2.2 Packaging material

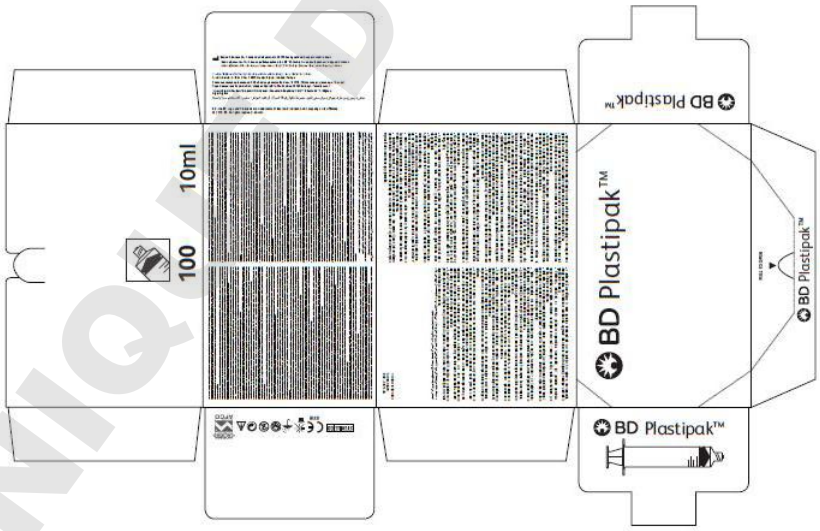
Component	Material
Unit Pack	Polyamide/polyethylene film Medical grade paper
Shelf Box	Corrugated carton
Shipping Case	Carton
IFU	Paper

2.3 Examples of labeling

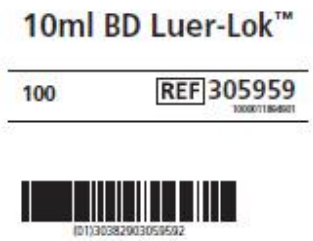
Labels: According to European Medical Device directive, labels are multilingual.

Unit Label extracted from document 10000118951 related to reference 305959:

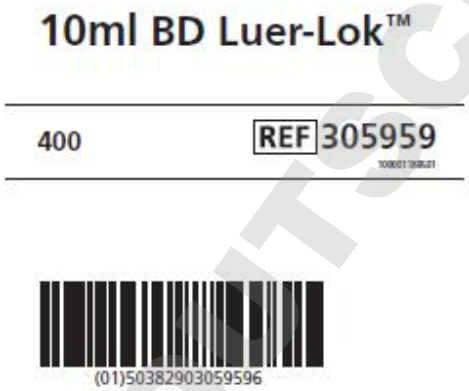
Shelf Box extracted from document 10000118948 related to reference 305959:



Shelf Label extracted from document 10000118949 related to reference 305959:



Shipping Case extracted from document 10000118950 related to reference 305959:



REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.3: Corrected manufacturing location for SKU 309653, 309654 and 309620.
03	Removing of the SKU 302188 throughout the TDS – *this SKU has been discontinued*