BD Plastipak™ Syringes without needle and BD® hypodermic Syringes without needle Sterile, Single-use

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TDS Number: V201-009 – Rev. 05
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1. General Information

1.1 Intended use

Legal Manufacturer	Intended use
Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín del Guadalix (Madrid) Spain	These BD Plastipak™ Syringes without needle are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA	These BD® hypodermic Syringes are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapore	These BD® hypodermic Syringes are single use devices, sold to healthcare professionals, used for general purpose injection and aspiration of medical fluids, or pharmaceuticals. These syringes are sold without needle.

1.2 General description

The BD® hypodermic Syringes and BD Plastipak™ Syringes assembly consists of a plastic barrel imprinted with a graduated scale and polypropylene plunger rod with a stopper affixed to the end. The BD® hypodermic Syringes and BD Plastipak™ Syringes are sold without needle, sterile, single-use.

General features of the BD Plastipak™ Syringes are as follows:

- Clear barrel for visualization of syringe content
- Bold scale printing to aid in setting for a more accurate dosage of medication
- Smooth plunger movement ensured by silicone lubrication of the stopper and barrel
- Leak-tight (locking facility on BD Luer-Lok™ syringes)

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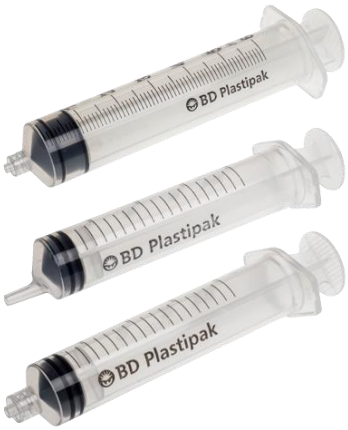

Figure 1: BD Plastipak™ Syringes

Figure 2: BD® hypodermic Syringe

Figure 3: BD® hypodermic Syringe 1mL SKU 309628

BD Catalog Number	BD Product Description	Capacity	Scale	Tip
309628	BD® Syringe 1 mL Luer-Lok™ Tip	1 mL	0.01 mL	Luer-lock concentric
303172	BD Plastipak™ Syringe 1 mL Luer Slip Tip	1 mL	0.01 mL	Luer slip concentric
303173	BD Plastipak™ Syringe 1 mL Luer Slip Tip Insulin U-40	1 mL	1 I.U.*	Luer slip concentric
303174	BD Plastipak™ Syringe 1 mL Luer Slip Tip Insulin U-100	1 mL	2 I.U.*	Luer slip concentric
309658	BD® Syringe 3 mL Luer-Lok™ Tip Euro	3 mL	0.1 mL	Luer-lock concentric
309649	BD® Syringe 5 mL Euro Luer-Lok™ Tip	5 mL	0.2 mL	Luer-lock concentric
302236[1]	BD® Syringe 5 mL Luer Slip Tip with red plunger for Anaesthetic Purposes	5 mL	0.2 mL	Luer slip concentric
305959	BD Plastipak™ Syringe 10 mL Luer-Lok™ Tip	10 mL	0.2 mL	Luer-lock concentric
300912	BD® Syringe 10 mL Luer-Lok™ Tip Eurographics	10 mL	0.2 mL	Luer-lock concentric
302146	BD® Syringe 10 mL Eccentric Luer Slip Tip	10 mL	0.2 mL	Luer slip eccentric
300629	BD Plastipak™ Syringe 20 mL Luer-Lok™ Tip	20 mL	1 mL	Luer-lock concentric
301189	BD Plastipak™ Syringe 20 mL Luer-Lok™ Tip	20 mL	1 mL	Luer-lock concentric
302830	BD® Syringe 20 mL Luer-Lok™ Tip	20 mL	1 mL	Luer-lock concentric
300613	BD Plastipak™ Syringe 20 mL Eccentric Luer Slip Tip	20 mL	1 mL	Luer slip eccentric
301183	BD Plastipak™ Syringe 20 mL Eccentric Luer Slip Tip	20 mL	1 mL	Luer slip eccentric
301229	BD Plastipak™ Syringe 30 mL Luer-Lok™ Tip	30 mL	1 mL	Luer-lock concentric
302832	BD® Syringe 30 mL Luer-Lok™ Tip	30 mL	1 mL	Luer-lock concentric

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BD Catalog Number	BD Product Description	Capacity	Scale	Tip
301231	BD Plastipak™ Syringe 30 mL Eccentric Luer Slip Tip	30 mL	1 mL	Luer slip eccentric
300865	BD Plastipak™ Syringe 50 mL Luer-Lok™ Tip	50 mL	1 mL	Luer-lock concentric
300869	BD Plastipak™ Syringe 50 mL Luer-Lok™ Tip Amber	50 mL	1 mL	Luer-lock concentric
309653	BD® Syringe 50 mL Luer-Lok™ Tip	50 mL	1 mL	Luer-lock concentric
300866	BD Plastipak™ Syringe 50 mL Eccentric Luer Slip Tip	50 mL	1 mL	Luer slip eccentric
300867	BD Plastipak™ Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter tip concentric
309620	BD® Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter tip concentric
300605	BD Plastipak™ Syringe 100 mL Catheter Tip	100 mL	2 mL	Catheter tip concentric

*I.U.: International Unit

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.

[1] Across BD, we routinely refine our product portfolio to serve our customers and patients more effectively. In our continuing effort to improve customer experience and streamline our broad product offering, we would like to inform you that the product SKU 302236 will be discontinued effective from the 31st of December 2022. For more information on the end date of the sales in your country, please contact your BD sales representative.

[2] The product SKU 305272 BD Integra™ Syringe 3mL with Needle 22GA 1-1/2IN (described in TDS V201-056 Integra™ Syringes w-wo Needle Sterile) will be discontinued effective from the 30th of September 2022. This product SKU 305272 will be replaced by two alternatives, the product SKU 302113 BD® Syringe 3 mL Luer-Lok™ Tip and the product SKU 303304 BD Eclipse™ needle 23GA 1-1/2IN. For more information on the end date of the sales in your country, please contact your BD sales representative.

The product SKU 302113, described in the table below, is a new product configuration and is sold sterile, single-use. For more information on the availability of this product in your country, please contact your BD sales representative.

BD Catalog Number	BD Product Description	Capacity	Scale Graduation	Tip
302113[2]	BD® Syringe 3 mL Luer-Lok™ Tip	3 mL	0.1 mL	Luer-lock concentric

Further features:

BD Plastipak™ Amber Syringes, such as 300869, have the barrel colored to reduce U.V. light for administration of light sensitive medications. The light transmission has been characterized by a transparency test. The transmission does not exceed 15% at any wavelength between 290 nm to 450 nm.

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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 del Guadalix (Madrid) Spain **ISO 13485** Certificate Number: 2012 07 0013 EN	CE certified with AEMPS (0318) Certificate Number: 95 06 0005 CP	**Address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín del Guadalix (Madrid) Spain **ISO 13485** Certificate Number: 2012 07 0013 EN	N/A
303174 303173 303172 300866 301231 300613 301183 300867 300605		CE certified with AEMPS (0318) Certificate Number: 2000 06 0273 CP		
302146 302236 302113	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapore **ISO 13485** Certificate Number: MD 81426	CE certified with BSI (2797) Certificate Number: CE 01487	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapore **ISO 13485** Certificate Number: MD 81426	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse, Belgium
302830 302832 309653 309620	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA **ISO 13485** Certificate Number: MD19.2305	CE certified with NSAI (0050) Certificate Number: 252.231	**Address:** BD Medical Surgical Systems 2153 12th Avenue Columbus, NE 68601, USA **ISO 13485** Certificate Number: MD19.2143	
309628 309658[3] 309649 300912			**Address:** Becton, Dickinson and Company Route 7 & Grace Way Canaan, CT 06018, USA **ISO 13485** Certificate Number: MD19.2369	
309658[3]			**Address:** BD Medical-Diabetes Care 1329 West Highway 6 Holdrege, NE 68949, USA **ISO 13485** Certificate Number: MD19.1436	

[3] The product SKU 309658 is manufactured in both Canaan and Holdrege manufacturing sites.

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1.4 Materials

Component	Material
Barrel	Polypropylene (except SKU 309628 BD® Syringe 1 mL Luer-Lok™ Tip is polycarbonate)
Plunger	Polypropylene
Stopper	Latex free elastomer
Lubricant	Medical grade silicone oil, <0.25mg/cm^2
Scale	Ink + dissolvent

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, 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), 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, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per, 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). **For SKU 309628:** 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 acid and related substances derived from tallow derivatives.

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Material	Comment
Substances of animal origin BSE/TSE	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).
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.
California Prop 65 chemicals	Based upon the review of raw materials, our production processes, and typical use cases for the products listed above, no potential exposures to any California Proposition 65 listed chemicals are projected to occur at a level that pose a "significant risk" as defined in the law. No labeling for California Prop 65 is needed.
Heavy metals and brominated flame retardants	Based on our ongoing data collection efforts and/or information received from our suppliers, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products. Furthermore, based on our ongoing data collection efforts and/or information received from our suppliers as of 17 March 2022, BD has not identified any bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) in an individual concentration above 0.1% w/w in the above-listed products.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers, BD has not identified any chemicals in the article and packaging with the product number 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 2022 according to Art. 59 (1,10) of the Regulation (EC) No 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.

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1.8 Sterilization method

- For products SKUs 300605, 300613, 300629, 300865, 300866, 300867, 300869, 301183, 301189, 301229, 301231, 302146, 302113, 302236, 303172, 303173, 303174, 305959: the sterilization method is validated per EN ISO 11135-1: Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. ETO residues are within applicable regulations.

- For products SKUs 300912, 302830, 302832, 309620, 309628, 309649, 309653, 309658: the sterilization method is validated per EN ISO 11137-1: Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Data to support re-sterilization of these products by the customer may be available through customer quality agreement with BD. The customer is responsible for validation of their own sterilization processes ensuring that the parameters used are not harsher than those defined by BD.

1.9 Shelf life and storage conditions

The BD® hypodermic Syringes and 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® hypodermic Syringes and BD Plastipak™ Syringes have a shelf life of 5 years, except SKU 300605 which has a shelf life of 18 months.

Note:

- Shelf life: Processing by the user, such as re-sterilization, might impact the shelf life of the product(s).
- BD recommends to store in a dry and warm place, not exposed to strong light.

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1.10 Standards

As per extract from the Declaration of Conformity (DoC_BD_Plastipak_Class_I_Rev_11) linked to CE certificate number 2000 06 0273 CP, related to product SKUs 300605, 300613, 300866, 300867, 301183, 301231, 303172, 303173 and 303174:

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 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 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
UNE-EN ISO 11135:2015	Sterilization of health-care products --. Ethylene oxide
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
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

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.

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As per extract from the Declaration of Conformity (EU_DoC_BD_Plastipak_Perfusion_BFN_ Class_IIa_Rev_6) linked to CE certificate number 95 06 0005 CP, related to product SKUs 300629, 300865, 300869, 301189, 301229 and 305959:

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 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 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN ISO 7864:2016	Sterile hypodermic needles for single use.
ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices.
EN ISO 6009:2016	Sterile hypodermic needles for single use. Identification color coding
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
UNE-EN ISO 11135:2015	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
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

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.

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As per extract from the Declaration of Conformity (DTF0001DOC_6-22-2022) linked to CE certificate number 252.231, related to product SKUs 300912, 302830, 302832, 309620, 309628, 309649, 309653 and 309658:

Standards	
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN 1707:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings
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 8537:2007	Sterile single-use syringes, with or without needle, for insulin
EN ISO 10993 series	Biological evaluation of medical devices – Parts 1-7, 9-18 and 23
EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 20594-1:1993	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Other Certain Medical Equipment – Part 1: General Requirements
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
ISO 7886-1:1993 COR1 1995*, ISO 7886-1:2017* (10mL Canaan syringes only)	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
IEC 62366-1:2015+AMD2020	Medical devices –Part 1: Application of usability engineering to medical devices – Amendment 1
ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 23908:2011	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification
ISO 7864:1993	Sterile hypodermic needles for single-use – Requirements and test methods
ISO 7886-2:1996*	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps
ISO 9626:1991 AMD1 2001	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods

*with exceptions

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As per extract from the Declaration of Conformity (TF000002-DEC (SG) rev 15) linked to CE certificate number CE 01487, related to product SKUs 302113, 302146 and 302236:

Standards	
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 116071:2006 /Amd.1:2014	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1
EN ISO 11607-2:2006 /Amd.1:2014	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1
EN ISO 11135-1:2014/Amd 1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1
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 - Amendment 2
EN ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ANSI/AQS Z1.4:2013	Sampling Procedures and Tables for Inspection by Attributes
ISO 594-1:1986 (with the exception of section 4.4 and 5.4)	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings
ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification
ISO 7864:1993	Sterile hypodermic needles for single use
ISO 7886-1:1993 /COR1:1995	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use — Technical Corrigendum 1
ISO 7886-2:1996	Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps

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1.11 Classification

- BD Plastipak™ Syringes products SKUs 300605, 300613, 300866, 300867, 301183, 301231, 303172, 303173 and 303174 are classified as Class I, sterile, with measuring function, Medical Device under Rule 2 of Annex IX of Medical Devices Directive 93/42/EEC as amended.

- The BD® hypodermic Syringes products SKUs 300912, 302113, 302146, 302236, 302830, 302832, 309620, 309628, 309649, 309653 and 309658 are classified as Class I, sterile, with measuring function, Medical Device under Rule 1, Annex IX of the Medical Device Directive 93\42\EEC as amended.

- The BD Plastipak™ Syringes products SKUs 300629, 300865, 300869, 301189, 301229 and 305959 are classified as Class IIa Medical Device under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD® hypodermic Syringes and 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, 309658, 300912, 303172, 305959, 300629, 301229, 300865, 300866, 300869, 301231, 300613, 309620.
GMDN Code: 35904 GMDN Term: Metered-delivery hypodermic syringe	302146, 302113, 302236, 303173, 303174.

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.

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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

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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*
309628	BD® Syringe 1 mL Luer-Lok™ Tip	1	100	800	Yes
303172	BD Plastipak™ Syringe 1 mL Luer Slip Tip	1	120	960	No
303173	BD Plastipak™ Syringe 1 mL Luer Slip Tip Insulin U-40	1	120	960	No
303174	BD Plastipak™ Syringe 1 mL Luer Slip Tip Insulin U-100	1	120	960	No
309658	BD® Syringe 3 mL Luer-Lok™ Tip Euro	1	200	800	Yes
302113	BD® Syringe 3 mL Luer-Lok™ Tip	1	100	800	No
309649	BD® Syringe 5 mL Euro Luer-Lok™ Tip	1	125	500	Yes
302236	BD® Syringe 5 mL Luer Slip Tip with red plunger for Anaesthetic Purposes	1	100	400	No
305959	BD Plastipak™ Syringe 10 mL Luer-Lok™ Tip	1	100	400	No
300912	BD® Syringe 10 mL Luer-Lok™ Tip Eurographics	1	100	400	Yes
302146	BD® Syringe 10 mL Eccentric Luer Slip Tip	1	100	400	No
300629	BD Plastipak™ Syringe 20 mL Luer-Lok™ Tip	1	120	480	No
301189	BD Plastipak™ Syringe 20 mL Luer-Lok™ Tip	1	60	480	No
302830	BD® Syringe 20 mL Luer-Lok™ Tip	1	48	192	No
300613	BD Plastipak™ Syringe 20 mL Eccentric Luer Slip Tip	1	120	480	No
301183	BD Plastipak™ Syringe 20 mL Eccentric Luer Slip Tip	1	60	240	No
301229	BD Plastipak™ Syringe 30 mL Luer-Lok™ Tip	1	60	240	No
302832	BD® Syringe 30 mL Luer-Lok™ Tip	1	56	224	No
301231	BD Plastipak™ Syringe 30 mL Eccentric Luer Slip Tip	1	60	240	No
300865	BD Plastipak™ Syringe 50 mL Luer-Lok™ Tip	1	60	240	No
300869	BD Plastipak™ Syringe 50 mL Luer-Lok™ Tip Amber	1	60	240	No
309653	BD® Syringe 50 mL Luer-Lok™ Tip	1	40	160	No
300866	BD Plastipak™ Syringe 50 mL Eccentric Luer Slip Tip	1	60	240	No
300867	BD Plastipak™ Syringe 50 mL Catheter Tip	1	60	240	No
309620	BD® Syringe 50 mL Catheter Tip	1	40	160	No
300605	BD Plastipak™ Syringe 100 mL Catheter Tip	1	50	100	No

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

2.2 Packaging material

Component	Material
Unit Pack	• Bottom web: Thermoformable plastic • Top web: Medical grade paper
Shelf Box	Corrugated carton
Shipping Case	Carton + Polyethylene Shrink-wrap Film
IFU (if applicable)	Paper

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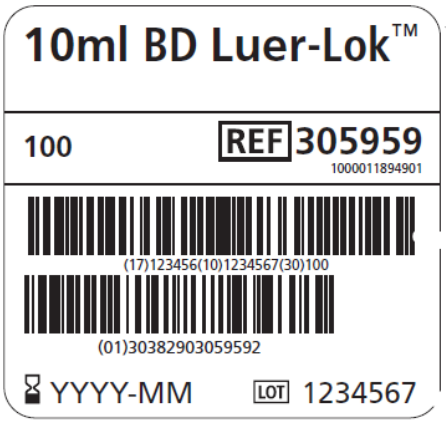
2.3 Examples of labeling

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

Unit Label extracted from document 10000118951 related to reference 305959:

Shelf Label extracted from document 10000118949 related to reference 305959:



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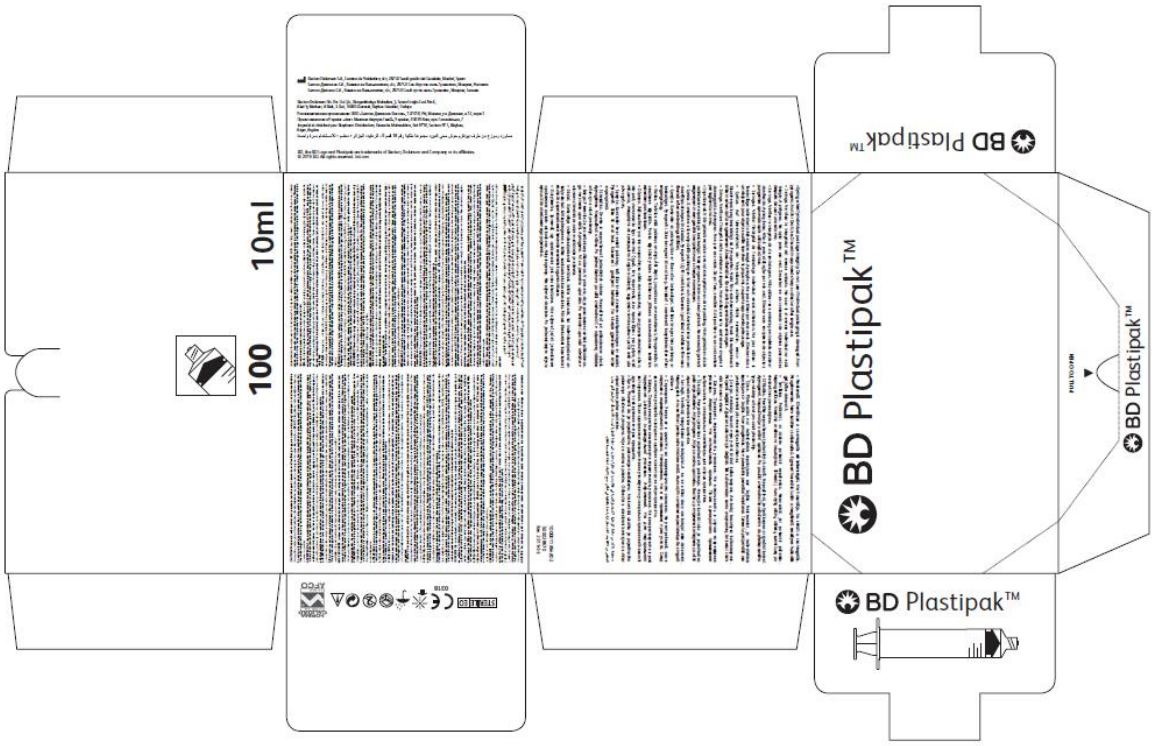
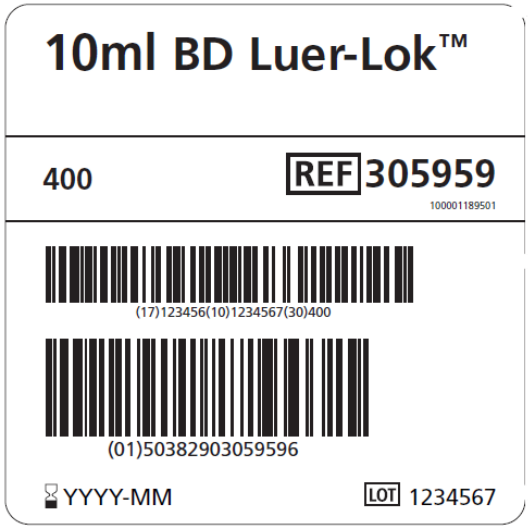
Shelf Box extracted from document 10000118948 related to reference 305959:



Shipping Case label extracted from document 10000118950 related to reference 305959:



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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*
04	Update of 1.2: General description Update of 2.1: Packaging configuration Update of 2.3: Examples of labelling
05	Update of: 1.1 Intended use 1.2 General description 1.3 Certification 1.4 Materials 1.5 Materials of concern 1.6 REACH information 1.8 Sterilization method 1.9 Shelf life and storage conditions 1.10 Standards 1.11 Classification 1.12 GMDN code 2.1 Packaging configuration 2.2 Packaging material Removal of product SKU 309654 from the TDS because there are no sales in EU.

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