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

BD® Plastipak™ Syringes without needle
Sterile, Single-use
Product codes:
303172 – 301183 – 300613 – 301231 –
300866 – 300867 – 300605 – 301189 – 300629 – 301229 –
300865 – 305959 – 300869

Becton Dickinson S.A–
San Agustín del Guadalix
Madrid, 28750, Spain

BD® Syringes without needle
Sterile, Single-use
Product codes:
302830 – 309653 – 309628 – 309658 – 309649 –
300912 – 302832 – 309620

Becton Dickinson and Company–
1 Becton Drive Franklin Lakes
New Jersey, 07417, USA

BD® Syringes without needle
Sterile, Single-use
Product codes:
302146

Becton Dickinson Medical (S) Pte
Ltd 30 Tuas Avenue 2
Singapore, 639461, Singapore

TDS number: V201-009 – Rev. 09
Veeva Number: BD-131227
2025-December

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1. General Information

1.1 Intended purpose

Plastipak™ Syringes without needle (SKUs: 303172, 301183, 300613, 301231, 300866, 301189, 300629, 301229, 300865, 305959, 300869) and **BD® Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 302146)** are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.

- **Catheter Tip Syringe (SKUs: 300867 and 309620) and Catheter Tip with Luer Slip Adaptor Syringe (SKU: 300605)**: these products are intended to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.

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1.2 Intended User

Plastipak™ Syringes without needle (SKUs: 303172, 301183, 300613, 301231, 300866, 300867, 300605, 301189, 300629, 301229, 300865, 305959, 300869) and **BD® Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620, 302146)** are to be used by medical practitioners (e.g. physicians, nurses, and pharmacists) experience in the use of the device. Experience may vary from novice to expert.

1.3 General Medical Devices description

Plastipak™ Syringes without needle (SKUs: 303172, 301183, 300613, 301231, 300866, 300867, 300605, 301189, 300629, 301229, 300865, 305959, 300869) assembly consists of a polypropylene barrel imprinted with a graduated scale and polypropylene plunger rod with a stopper affixed to the end. The design includes a retaining ring to prevent accidental plunger rod withdrawal. These syringes have been validated with BD® Alaris™ Infusion Pumps. These syringes are for single-use.

- SKU 303172 as plunger colorant has polypropylene-based white color concentrate.
- SKU 300869 as barrel colorant has polypropylene-based amber color concentrate.
- SKU 300605 is a Plastipak™ Syringe 100 mL Catheter Tip with an extractable Luer Slip Adaptor (Figure 3A).

BD® Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620) assembly consists of a polypropylene barrel imprinted with a graduated scale and polypropylene plunger rod with a synthetic rubber stopper affixed to the end (the BD® Syringe 1 mL Luer-Lok™ (**SKU 309628**) barrel is made of polycarbonate). Syringes in this TDS are sold without a needle. The syringes are packaged and sterilized (if applicable), single-use.

BD® Syringes without needle (SKUs: 302146) 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.

All the SKUs in this TDS except from the Catheter Tip (SKUs: 300867, 300605, 309620) are Luer compliant with ISO 80369-7:2021 (Refer to section 1.10 Standards).

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Figure 1: Plastipak™ Syringes without needle



Figure 2: BD® Syringes without needle

3A



3B

Figure 3:
3A: Plastipak™ Syringe 100 mL Catheter Tip with Luer Slip Adaptor (SKU: 300605)
3B: Plastipak™ Syringe 50 mL Catheter Tip (SKU: 300867)

BD Catalog Number	BD Product Description	Capacity	Scale	Tip	Additional information
Plastipak™ Syringes without needle					
303172	Plastipak™ Syringe 1 mL Luer Slip	1 mL	0.01 mL	Luer slip concentric	Plunger colorant: White.
305959	Plastipak™ Syringe 10 mL Luer-Lok™	10 mL	0.2 mL	Luer-lock concentric	N/A
300629	Plastipak™ Syringe 20 mL Luer-Lok™	20 mL	1 mL	Luer-lock concentric	N/A
301189	Plastipak™ Syringe 20 mL Luer-Lok™	20 mL	1 mL	Luer-lock concentric	N/A

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BD Catalog Number	BD Product Description	Capacity	Scale	Tip	Additional information
300613	Plastipak™ Syringe 20 mL Luer-Slip	20 mL	1 mL	Luer slip eccentric	N/A
301183	Plastipak™ Syringe 20 mL Luer-Slip	20 mL	1 mL	Luer slip eccentric	N/A
301229	Plastipak™ Syringe 30 mL Luer-Lok™	30 mL	1 mL	Luer-lock concentric	N/A
301231	Plastipak™ Syringe 30 mL Luer-Slip	30 mL	1 mL	Luer slip eccentric	N/A
300865	Plastipak™ Syringe 50 mL Luer-Lok™	50 mL	1 mL	Luer-lock concentric	N/A
300869	Plastipak™ Syringe 50 mL Luer-Lok™	50 mL	1 mL	Luer-lock concentric	Barrel colorant: Amber
300866	Plastipak™ Syringe 50 mL Luer-Slip	50 mL	1 mL	Luer slip eccentric	N/A
300867	Plastipak™ Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter Tip concentric	N/A
300605	Plastipak™ Syringe 100 mL Catheter Tip with Luer Slip Adaptor	100 mL	2 mL	Catheter Tip concentric	Luer Slip Adaptor
BD® Syringes without needle					
309628	BD® Syringe 1 mL Luer-Lok™	1 mL	0.01 mL	Luer-lock concentric	N/A
309658	BD® Syringe 3 mL Luer-Lok™	3 mL	0.1 mL	Luer-lock concentric	N/A
309649	BD® Syringe 5 mL Luer-Lok™	5 mL	0.2 mL	Luer-lock concentric	N/A
300912	BD® Syringe 10 mL Luer-Lok™	10 mL	0.2 mL	Luer-lock concentric	N/A
302830	BD® Syringe 20 mL Luer-Lok™	20 mL	1 mL	Luer-lock concentric	N/A
302832	BD® Syringe 30 mL Luer-Lok™	30 mL	1 mL	Luer-lock concentric	N/A
309653	BD® Syringe 50 mL Luer-Lok™	50 mL	1 mL	Luer-lock concentric	N/A
309620	BD® Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter Tip concentric	N/A
BD® Syringes without needle					
302146	BD® Syringe 10 mL Eccentric Tip	10 mL	0.2 mL	Luer slip eccentric	N/A

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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.

1.4 Certification

BD Catalog 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, CH Representative UK Representative (if applicable)
305959 301189 300629 301229 300865 300869	**Name and address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín del Guadalix (Madrid) Spain **ISO 13485** Certificate No.: MD 778147	**CE certified** with AEMPS (0318) MDD Certificate No.: 95 06 0005 CP (ART120 818297) **UKCA certified:** N/A	**Name and address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín del Guadalix (Madrid) Spain **ISO 13485** Certificate No.: MD 778147	N/A
303172 300866 301231 300613 301183 300867 300605		**CE certified** with AEMPS (0318) MDD Certificate No.: 2000 06 0273 CP (ART120 818302) **UKCA certified:** N/A		
302830 302832 309653 309620	**Name and address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA **ISO 13485** Certificate No.: MD19.2305	**CE certified** with NSAI (0050) MDD Certificate No.: 252.231 **UKCA certified:** N/A	**Name and address:** BD Medical Surgical Systems 2153 12th Avenue Columbus, NE 68601, USA **ISO 13485** Certificate No.: MD19.2143	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse, Belgium
309628 309649 309658 300912			**Name and address:** Becton, Dickinson and Company Route 7 & Grace Way Canaan, CT 06018, USA **ISO 13485** Certificate No.: MD19.2369	
302146	**Name and address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapure **ISO 13485** Certificate No.: 90731	**CE certified** with BSI (2797) MDD Certificate No.: CE 01487 **UKCA certified:** N/A	**Name and address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapure **ISO 13485** Certificate No.: 90731	

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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

As per extract from the Technical File IT-004, linked to CE certificate number 95 06 0005 CP related to product SKUs: 300629, 300865, 300869, 301189, 301229, 305959 and linked to CE certificate number 2000 06 0273 CP related to product SKUs: 303172, 300866, 301231, 300613, 301183, 300867, 300605:

Component	Material
Syringe Barrel	Polypropylene
Barrel Colorant	**Only for SKU 300869:** Amber
Barrel and stopper lubricant	Polydimethylsiloxane
Plunger	Polypropylene
Plunger colorant	**Only for SKU 303172**: Polypropylene-based white color concentrate
Stopper	Polyisoprene rubber
Scale mark	Printing ink mixture

As per extract from the Technical File DTF0001 linked to CE certificate number 252.231 related to product SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620:

Component	Material
Syringe Barrel	Polypropylene **Only for SKU 309628** (BD® Syringe 1 mL Luer-Lok™ Tip): Polycarbonate
Plunger rod	Polypropylene
Stopper	Polyisoprene
Barrel and stopper lubricant	Polydimethylsiloxane

As per extract from technical file TF000002 (SG) linked to CE certificate number CE 01487 related to product SKUs: 302146:

Component	Material
Syringe Barrel	Polypropylene
Plunger	Polypropylene
Stopper	Polyisoprene rubber / Styrene Butadiene rubber
Barrel lubricant	Polydimethylsiloxane

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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.

For the product SKUs listed in this Technical Data Sheet (TDS):

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 November 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), or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles 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 10 November 2025, 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 10 November 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). **For the 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 (bracketing studies), 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. This product is 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 224421:2020 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, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC, MDR 2017/745, and EU No 722/2012).

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Material	Comment
Polyvinyl chloride (PVC)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 November 2025, the medical devices 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.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 November 2025, BD has not identified any chemicals in the articles with the product numbers referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 27 June 2024 according to Art. 59 (1,10) of the Regulation (EC) No. 1907/2006 (REACH).

1.9 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices. BD tests biocompatibility on sterile products as that is considered worst case, these results can then be leveraged to non-sterile products.

1.10 Sterilization method

Plastipak™ Syringes without needle manufactured in San Agustín del Guadalix (SKUs: 303172, 301183, 300613, 301231, 300866, 300867, 300605, 301189, 300629, 301229, 300865, 305959, 300869) are sterilized using a gas mixture of Ethylene Oxide and CO2 (in the proportion 90:10).

BD® Syringes without needle manufactured in:

- **Canaan (SKUs: 309628, 309649, 309658 and 300912)** are sterilized using E-Beam.
- **Columbus (SKUs: 302830, 302832, 309653 and 309620)** are sterilized using Gamma Radiation.

BD® Syringes without needle manufactured in Tuas (SKU: 302146) are sterilized using a gas mixture of Ethylene Oxide (EO) and Nitrogen (N2).

1.11 Shelf life and storage conditions

The product SKUs in this Technical Data Sheet (TDS) shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

BD Catalog number	Shelf life
Plastipak™ Syringes without needle. SKUs: 303172, 301183, 300613, 301231, 300866, 300867, 301189, 300629, 301229, 300865, 305959, 300869.	5 years

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BD Catalog number	Shelf life
BD® Syringes without needles. SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620, 302146.	5 years
Plastipak™ Syringe 100mL Catheter Tip with Luer Slip Adaptor. SKU: 300605.	1.5 years (18 months)

Note:

- These devices are designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking into account the instructions and information provided within the device packaging.
- BD recommends to store in a dry and warm place, not exposed to strong light.

1.12 Applied Standards

As per extract from the Technical Documentation for **Plastipak™ Syringes** on the Technical File (IT-004) and on 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, 305959:**

Standard reference number	Title	Standard applied (Full or Partial)
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.	Full
EN 556-1:2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	Full
ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications part 7: connectors for intravascular or hypodermic applications	Full
EN ISO 13485:2016 / AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes.	Full
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	Full
EN ISO 7886-1 :2018	Sterile hypodermic syringe for single-use - Part 1: Syringes for manual use.	Full
EN ISO 7886-2:2020	Sterile hypodermic syringe for single-use - Part 2: Syringes for use with power-driven syringe pumps.	Partial*
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer.	Full
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Full
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	Full
EN ISO 11135:2014/A1:2019	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release.	Full
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.	Full

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Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products - Amendment 1.	Full
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.	Full
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements.	Full
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes.	Full
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Full
EN ISO 10993-2-:2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements.	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	Full
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.	Full
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Full
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	Full
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.	Full
EN ISO 10993-18:2020/A1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor.	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.	Full
ISO-14001:2015**	Environmental management systems — Requirements with guidance for use.	Full

*All Luer-Lok™ Tip syringes meet all sections of EN ISO 7886-2:2020 with the exception of Section 14.3 (short-term flow rate error). EN ISO 7886-2:2020 is not applicable for Luer Slip Tip and Catheter Tip syringes.

**The manufacturing sites of the products listed in this Technical Data Sheet are compliance with ISO-14001:2015.

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Standard reference number	Title	Standard applied (Full or Partial)
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.	Full
EN 556-1:2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	Full
ISO 80369-7:2021***	Small-bore connectors for liquids and gases in healthcare applications part 7: connectors for intravascular or hypodermic applications	Full
EN ISO 13485:2016 / AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes.	Full
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	Full
EN ISO 7886-1 :2018	Sterile hypodermic syringe for single-use - Part 1: Syringes for manual use.	Full
EN ISO 7886-2:2020	Sterile hypodermic syringe for single-use - Part 2: Syringes for use with power-driven syringe pumps.	Partial*
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer.	Full
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Full
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	Full
EN ISO 11135:2014 /A1:2019	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release.	Full
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.	Full
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products - Amendment 1.	Full
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.	Full
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements.	Full
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes.	Full
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Full
EN ISO 10993-2-:2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements.	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	Full

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Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.	Full
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Full
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	Full
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.	Full
EN ISO 10993-18:2020/A1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor.	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.	Full
ISO-14001:2015**	Environmental management systems — Requirements with guidance for use.	Full

*All Luer-Lok™ Tip syringes meet all sections of EN ISO 7886-2:2020 with the exception of Section 14.3 (short-term flow rate error). EN ISO 7886-2:2020 is not applicable for Luer Slip Tip and Catheter Tip syringes.

**The manufacturing sites of the products listed in this Technical Data Sheet are compliance with ISO-14001:2015.

***EN ISO 80369-7:2021 is not applicable for Catheter Tip Syringes (SKUs: 300867, 300605, 309620).

As per extract from the Technical Documentation for the **BD® Syringes** on the Technical File (DTF0001) and on the Declaration of Conformity (DOC DTF0001) linked to CE certificate number 252.231, related to product **SKUs: 300912, 302830, 302832, 309620, 309628, 309649, 309653 and 309658.**

Standard reference number	Title	Standard applied (Full or Partial)
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.	Full
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes.	Full
EN ISO 14971:2019	Medical devices – Application of Risk Management to Medical Devices.	Full
ISO 80369-7:2021***	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.	Full
EN ISO 20417:2021	Medical devices - Information supplied by the manufacturer of medical devices.	Full
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.	Full
ISO 7886-1:2018	Sterile hypodermic syringes for single-use – Part 1: Syringes for manual use.	Full

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Standard reference number	Title	Standard applied (Full or Partial)
ISO 7886-2:2020	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps.	Partial*
EN 556-1: 2001/AC: 2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Requirements for terminally sterilized medical devices.	Full
EN ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products.	Full
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.	Full
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.	Full
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Establishing the sterilization dose.	Full
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators – Part 1: General requirements.	Full
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Full
EN ISO 10993-2-:2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements.	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	Full
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.	Full
EN ISO 10993-9:2021	Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products.	Full
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Full
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	Full
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.	Full
ISO-14001:2015**	Environmental management systems — Requirements with guidance for use.	Full

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*All syringe sizes meet all sections of EN ISO 7886-2:2020 with the exception of Section 14.3 (short-term flow rate error). Full justification rationale for this exception can be found in FSRS for BD® Syringes (document 10000532358).

**The manufacturing sites of the products listed in this Technical Data Sheet are compliance with ISO-14001:2015.

***EN ISO 80369-7:2021 is not applicable for Catheter Tip Syringes (SKUs: 300867, 300605, 309620).

As per extract from the Technical Documentation for the **BD® Syringes** on the Technical File (TF000002 (SG)) and on the Declaration of Conformity (TF000002-DEC (SG) rev 15) linked to CE certificate number CE 01487, related to product **SKUs: 302146.**

Standard reference number	Title	Standard applied (Full or Partial)
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.	Full
EN ISO 13485:2016 / AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes.	Full
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.	Full
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.	Full
EN ISO 20417:2021	Medical devices - Information supplied by the manufacturer of medical devices.	Full
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Full
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	Full
EN ISO 11135 :2014/A1 :2019	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	Full
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.	Full
EN 556-1: 2001/AC: 2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Requirements for terminally sterilized medical devices.	Full
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators – Part 1: General requirements.	Full
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes.	Full
ISO 7886-1:2018	Sterile hypodermic syringes for single-use – Part 1: Syringes for manual use.	Full
ISO 7886-2:2020	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps.	Partial*
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Full
EN ISO 10993-2-:2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements.	Full
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for	Full

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Standard reference number	Title	Standard applied (Full or Partial)
	interactions with blood.	
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	Full
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.	Full
EN ISO 10993-9:2021	Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products.	Full
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Full
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	Full
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.	Full
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.	Full
ISO-14001:2015**	Environmental management systems — Requirements with guidance for use.	Full

*BD Syringes complies with ISO 7886-2 with an exception to section 14.3.

**The manufacturing sites of the products listed in this Technical Data Sheet are compliance with ISO-14001:2015.

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

1.13 Classification

BD Catalog number	Classification
303172, 300866 301231, 300613 301183, 300867 300605	**Plastipak™ Syringes** are Class I, sterile, with a measuring function, under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.
305959, 301189 300629, 301229 300865, 300869	**Plastipak™ Syringes** are Class IIa under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.
302830, 302832, 309653, 309620, 309628, 309649, 309658, 300912	**BD® Syringes without needles** are Class I sterile with a measuring function, under Rule 1 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.
302146	**BD® Syringes without needles** are Class I sterile with a measuring function (Is/Im), under Rule 1 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.

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1.14 Medical Device Nomenclature

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), the product SKUs listed in this TDS are referenced as follows:

	BD Catalog number	GMDN
Plastipak™ Syringes without needle	303172, 300866, 301231, 300613, 301183, 300867, 300605305959, 301189, 300629, 301229, 300865, 300869	**GMDN Code**: 47017 **GMDN Term**: General Purpose Syringe, single-use
BD® Syringes without needles	302830, 302832, 309653, 309628, 309649, 309658, 300912	**GMDN Code**: 47017 **GMDN Term**: General Purpose Syringe, single-use
	309620	**GMDN Code**: 35904 **GMDN Term:** Metered Delivery Hypodermic Syringe
BD® Syringes without needles	302146	**GMDN Code**: 35904 **GMDN Term**: Injection Syringe, single-use

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 FDA Pharmaceutical are not applicable for 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*
Plastipak™ Syringes without needle					
303172	Plastipak™ Syringe 1 mL Luer Slip	1	120	960	No
305959	Plastipak™ Syringe 10 mL Luer-Lok™	1	100	400	No
300629	Plastipak™ Syringe 20 mL Luer-Lok™	1	120	480	No
301189	Plastipak™ Syringe 20 mL Luer-Lok™	1	60	240	No
300613	Plastipak™ Syringe 20 mL Luer-Slip	1	120	480	No
301183	Plastipak™ Syringe 20 mL Luer-Slip	1	60	240	No
301229	Plastipak™ Syringe 30 mL Luer-Lok™	1	60	240	No
301231	Plastipak™ Syringe 30 mL Luer-Slip	1	60	240	No
300865	Plastipak™ Syringe 50 mL Luer-Lok™	1	60	240	No
300869	Plastipak™ Syringe 50 mL Luer-Lok™	1	60	240	No
300866	Plastipak™ Syringe 50 mL Luer-Slip	1	60	240	No
300867	Plastipak™ Syringe 50 mL Catheter Tip	1	60	240	No
300605	Plastipak™ Syringe 100 mL Catheter Tip with Luer Slip Adaptor	1	25	50	No
BD® Syringes without needle					
309628	BD® Syringe 1 mL Luer-Lok™	1	100	800	Yes
309658	BD® Syringe 3 mL Luer-Lok™	1	200	800	Yes
309649	BD® Syringe 5 mL Luer-Lok™	1	125	500	Yes
300912	BD® Syringe 10 mL Luer-Lok™	1	100	400	Yes
302830	BD® Syringe 20 mL Luer-Lok™	1	48	192	No
302832	BD® Syringe 30 mL Luer-Lok™	1	56	224	No
309653	BD® Syringe 50 mL Luer-Lok™	1	40	160	No
309620	BD® Syringe 50 mL Catheter Tip	1	40	160	No
BD® Syringes without needle					
302146	BD® Syringe 10 mL Eccentric Tip	1	100	400	No

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

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2.2 Packaging material

As per extract from the technical file IT-004, linked to CE certificate number 95 06 0005 CP related to product SKUs: 300629, 300865, 300869, 301189, 301229, 305959 and linked to CE certificate number 2000 06 0273 CP related to product SKUs: 303172, 300866, 301231, 300613, 301183, 300867, 300605:

Component	Material
Top Web	Paper
Bottom web	Polyamide/Polyethylene
Shelf Carton	Corrugated carton

As per extract from DTF0001 linked to CE certificate number 252.231 related to product SKUs 300912, 302830, 302832, 309620, 309628, 309649, 309653 and 309658.

Component	Material
Top Web	Medical grade paper/Plastic film
Bottom Web	Medical grade packaging substrate/Thermoformable plastic film
Shelf Package	Corrugated carton

As per extract from technical file TF000002 (SG) linked to CE certificate number CE 01487 related to product SKUs: 302146:

Component	Material
Top Web	Medical Grade Paper
Botton Web	Nylon Film
Shelf Carton	Corrugated Paper Pulp
Cube Pack	Polyethylene Shrink-wrap Film

2.3 Recycled material 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.

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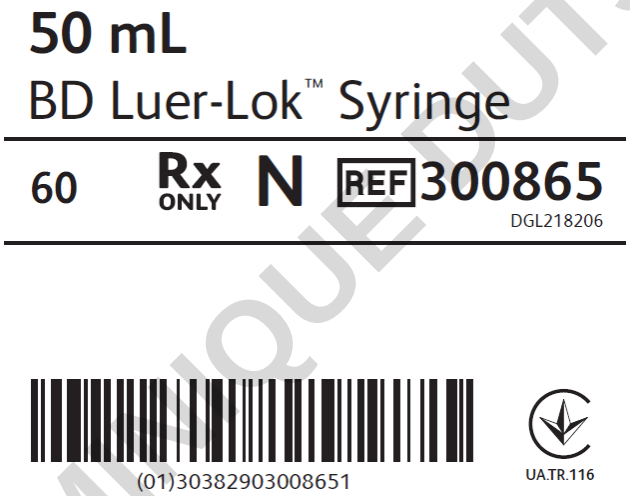
2.4 Examples of labeling

Labeling for Plastipak™ Syringe 50 mL Luer-Lok™ (SKU: 300865)

Unit Label extracted from document DGW1084 rev.09 related to reference 300865:



Shelf Label extracted from document DGL2182 rev.06 related to reference 300865:

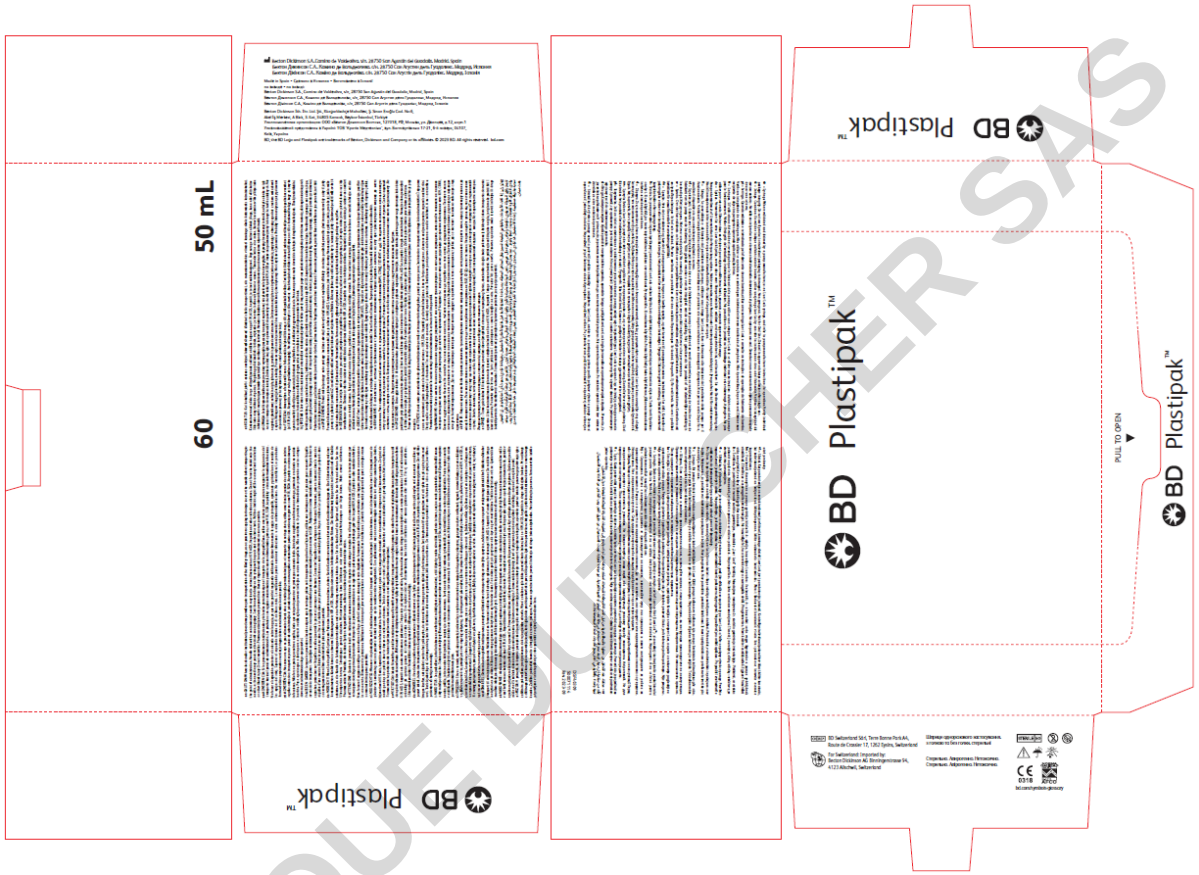


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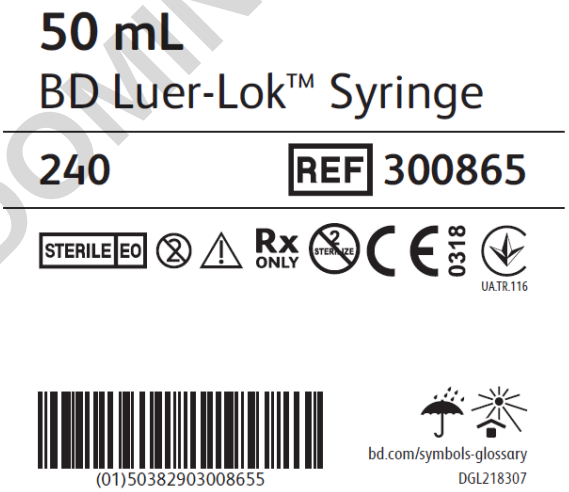
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Shelf Carton extracted from document DGF403 rev.09 related to reference 300865:



Case label extracted from document DGL2183 rev.07 related to reference 300865:



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Labeling for BD® Syringe 1 mL Luer-Lok™ (SKU: 309628):

Unit Label extracted from document DGW757 rev.07 related to reference 309628:



Shelf Label extracted from document DGL1437 rev.03 related to reference 309628:

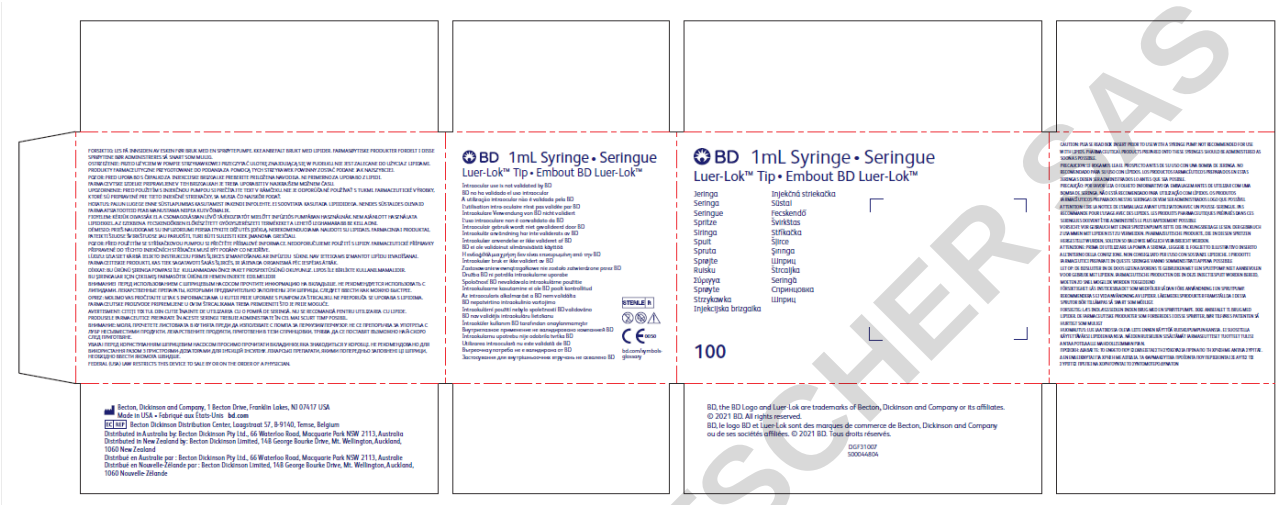


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Shelf Carton extracted from document DGF310 rev.07 related to reference 309628:



Case Label extracted from document DGL2232 rev.04 related to reference 309628:



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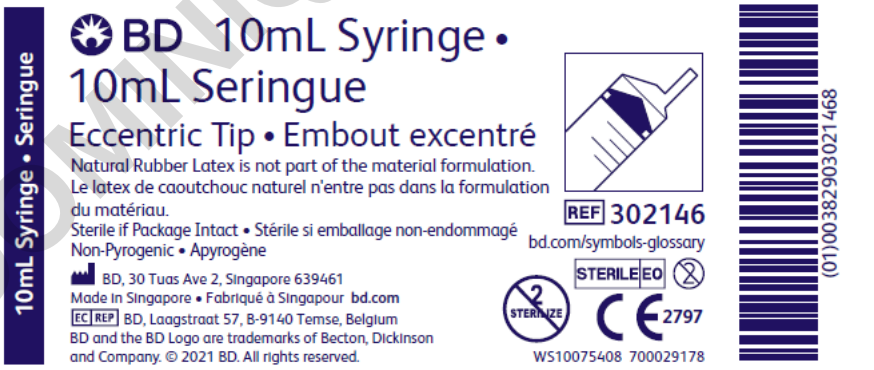
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IFU insert extracted from document DGP67 rev.03 related to reference 309628:



Labeling for BD® Syringe 10 mL Eccentric Tip (SKU: 302146)

Unit Label extracted from document WS100754 rev.08 related to reference 302146:



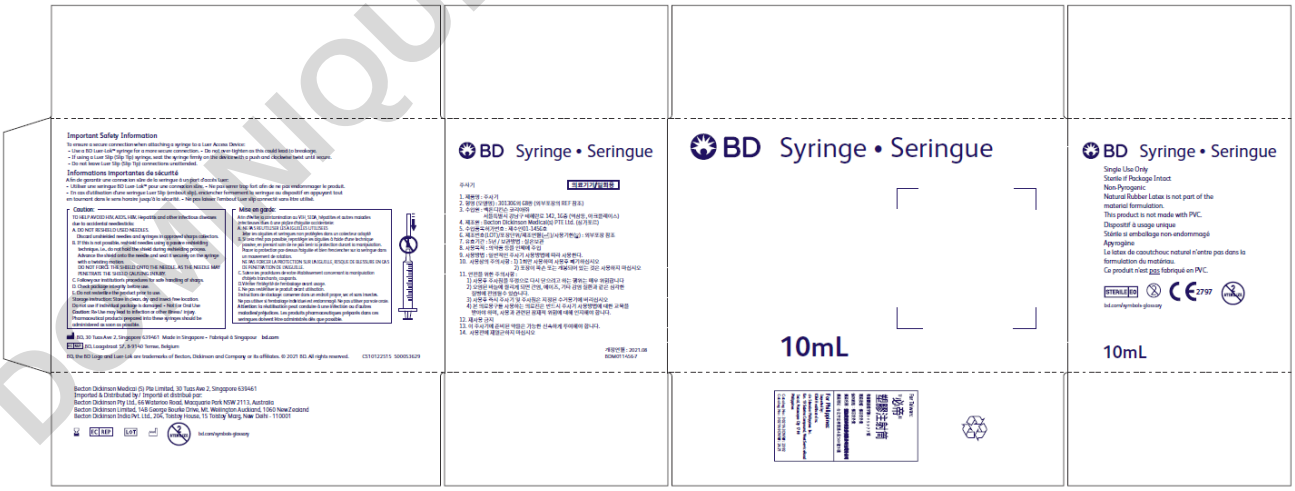
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Shelf Label extracted from document SDGL34 rev.03 related to reference 302146:



Shelf Carton extracted from document CS101225 rev.15 related to reference 302146:



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Case Label extracted from document SDGL35 rev.05 related to reference 302146:



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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.
06	Initial release according to new template: Addition of codes 302100, 302204, 302106, 302130, 302135, 302143, 302149, 302831, 302833, 303288, 309654. Update of: • 1.2 General Medical Device Description • 1.3 Certification • 1.13 Standards • 2.1 Packaging configuration Update to better reflect the technical file: • 1.7 Materials • 2.2 Packaging Material
07	Removal of codes 302135 and 302236 discontinued 1.2 General medical devices description: Correction of inaccurate product descriptions 1.15 Medical Device Nomenclature: change of the wording Change of the layout covering all the document Change of figures numbers and titles
08	Release according to new template EMEA-SOP039-F1 as per technical file numbers: • IT-004, version 40 published in May 05th 2023 • DTF000, version AF published in Jan 23th 2024 • TF000002 (SG), version 32 published in Sep 25th 2023 Remove SKUs: 302100, 302204, 302106, 302130, 302143, 302149, 302188, 302831, 302833, 303288 and 309654.
09	Remove SKUs: 303174, 303173 and 302113. Update of 1.10: Standards.

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