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BD Plastipak™ Syringes without needle
Sterile, Single-use
Product codes:
303174 – 303173 – 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® hypodermic 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® hypodermic Syringes without needle
Sterile, Single-use
Product codes:
302146 – 302113

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

TDS number: V201-009 – Rev. 08
Veeva Number: BD-131227
2024-June

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1. General Information

1.1 Intended purpose

BD Plastipak™ Syringes without needle (SKUs: 303174, 303173, 303172, 301183, 300613, 301231, 300866, 300867*, 300605*, 301189, 300629, 301229, 300865, 305959, 300869) 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.
***Catheter Tip Syringe**

BD® hypodermic Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620*) 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:** These products are intended to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound

BD® hypodermic Syringes without needle (SKUs: 302146, 302113) are single-use devices, used for general purpose injection and aspiration of medical fluids, or pharmaceuticals.

1.2 Intended User

Plastipak™ Syringes without needle (SKUs: 303174, 303173, 303172, 301183, 300613, 301231, 300866, 300867, 300605, 301189, 300629, 301229, 300865, 305959, 300869) are to be used by medical practitioners (e.g. physicians, nurses, nurse practitioner, and pharmacists) or laypersons trained in the use of the syringe (DR4). Experience level will be from novice to expert. Minimal to no training is required for the operation of conventional syringes.

BD® hypodermic Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620) are to be used by medical practitioners (e.g. physicians, nurses, nurse practitioners, and pharmacists) or laypersons trained in the use of the syringe. Experience may vary from novice to expert. Minimal to no training is required for operation of conventional syringes.

The users of the **BD® hypodermic Syringes without needle (SKUs: 302146, 302113)** are normally medical professionals who are trained to use hypodermic syringes.

1.3 General Medical Devices description

Plastipak™ Syringes without needle (SKUs: 303174, 303173, 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. These syringes are for single-use. They can be manufactured transparent or amber just to protect drugs from light.

BD® hypodermic 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/ thermoplastic elastomers stopper affixed to the end. The (1ml Luer-Lok syringe (**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® hypodermic Syringes without needle (SKUs: 302146, 302113) 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.

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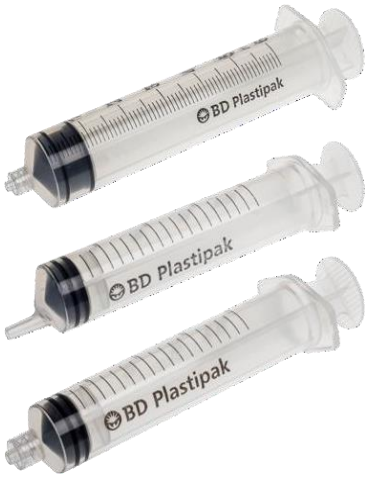

Figure 1: Plastipak™ Syringes

Figure 2: BD® Hypodermic Syringes

BD Catalog Number	BD Product description	Capacity	Scale	Tip	Additional information
309628	BD® Syringe 1 mL LL w/o DN (without Detached Needle)	1 mL	0.01 mL	Luer-Lok Tip™ concentric	N/A
303172	Plastipak™ Syringe 1 mL Luer SP120 (Packaging units)	1 mL	0.01 mL	Luer-Slip Tip™ concentric	N/A
303173	Plastipak™ Syringe 1 mL Luer Insulin U-40 SP120	1 mL	1 I.U.*	Luer-Slip Tip™ concentric	Scale: Insulin U-40
303174	Plastipak™ Syringe 1 mL Luer without needle U-100 SP120 (Packaging units)	1 mL	2 I.U.*	Luer-Slip Tip™ concentric	Scale: Insulin U-100
309658	BD® Syringe 3 mL LL EURO 200 S/C (200 units per Shelf Carton)	3 mL	0.1 mL	Luer-Lok Tip™ concentric	N/A
302113	BD® Syringe 3 mL Luer-Lok™ Tip	3mL	0,1 mL	Luer-Lok Tip™ concentric	N/A
309649	BD® Syringe 5 mL LL EURO 125 S/C (125 units per Shelf Carton)	5 mL	0.2 mL	Luer-Lok Tip™ concentric	N/A
305959	Plastipak™ Syringe 10 mL Luer-Lok™	10 mL	0.2 mL	Luer-Lok Tip™ concentric	N/A
300912	BD® Syringe 10 mL (only[1]) Eurographics	10 mL	0.2 mL	Luer-Lok Tip™ concentric	N/A
302146	BD® Syringe 10 mL Eccentric Tip	10 mL	0.2 mL	Luer-Slip Tip™ eccentric	N/A
300629	Plastipak™ Syringe 20 mL Luer-Lok	20 mL	1 mL	Luer-Lok Tip™ concentric	N/A
301189	Plastipak™ Syringe 20 mL Luer-Lok	20 mL	1 mL	Luer-Lok Tip™ concentric	N/A

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BD Catalog Number	BD Product description	Capacity	Scale	Tip	Additional information
302830	BD® Syringe 20 mL LL (48 per box)	20 mL	1 mL	Luer-Lok Tip™ concentric	N/A
300613	Plastipak™ Syringe 20 mL Luer-Slip	20 mL	1 mL	Luer-Slip Tip™ eccentric	N/A
301183	Plastipak™ Syringe 20 mL Luer-Slip	20 mL	1 mL	Luer-Slip Tip™ eccentric	N/A
301229	Plastipak™ Syringe 30 mL Luer-Lok	30 mL	1 mL	Luer-Lok Tip™ concentric	N/A
302832	BD® Syringe 30 mL Luer-Lok (56 per box)	30 mL	1 mL	Luer-Lok Tip™ concentric	N/A
301231	Plastipak™ Syringe 30 mL Luer-Slip	30 mL	1 mL	Luer-Slip Tip™ eccentric	N/A
300865	Plastipak™ Syringe 50 mL Luer-Lok	50 mL	1 mL	Luer-Lok Tip™ concentric	N/A
300869	Plastipak™ Syringe 50 mL Luer-Lok Amber	50 mL	1 mL	Luer-Lok Tip™ concentric	Amber
309653	BD® Syringe 50 mL Luer-Lok	50 mL	1 mL	Luer-Lok Tip™ concentric	N/A
300866	Plastipak™ Syringe 50 mL Luer-Slip	50 mL	1 mL	Luer-Slip Tip™ eccentric	N/A
300867	Plastipak™ Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter Tip concentric	N/A
309620	BD® Syringe 50 mL Catheter Tip	50 mL	1 mL	Catheter Tip concentric	N/A
300605	Plastipak™ Syringe 100 mL CT	100 mL	2 mL	Catheter Tip concentric	N/A

[1] « Only » indicates that the SKU is a syringe only, not a syringe/needle combo product

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 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 No.: MD 778394	CE certified with AEMPS (0318) Certificate No.: 95 06 0005 CP	**Address:** Becton Dickinson S.A. Camino Valdeoliva s/n 28750 San Agustín del Guadalix (Madrid) Spain **ISO 13485** Certificate No.: MD 778394	N/A
303174 303173 303172 300866 301231 300613 301183 300867 300605		CE certified with AEMPS (0318) Certificate No.: 2000 06 0273 CP		
302830 302832 309653 309620	**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) Certificate No.: 252.231	**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			**Address:** Becton, Dickinson and Company Route 7 & Grace Way Canaan, CT 06018, USA **ISO 13485** Certificate No.: MD19.2369	
302113 302146	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapore **ISO 13485** Certificate No.: MD 81426	CE certified with BSI (2797) Certificate No.: CE 01487	**Address:** Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461, Singapore **ISO 13485** Certificate No.: MD 81426	

1.5 UDI-DI and Basic UDI-DI

The product SKUs in this Technical Data Sheet (TDS) are CE certified under Medical Device Directive (MDD). BD is transitioning to Medical Device Regulation (MDR), and as the information in this section is the requirement of MDR, it is still not available. The TDS 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: 303174, 303173, 303172, 300866, 301231, 300613, 301183, 300867, 300605:

Component	Material
Syringe Barrel	Polypropylene
Barrel Colorant	**For SKU 300869:** Amber
Barrel lubricant	Medical grade silicone
Plunger	Polypropylene
Plunger colorant	PE/F
Stopper	Polyisoprene black rubber or Black TPE Copolymer
Scale	Ink/Dissolvent

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 (except SKU 309628 BD® Syringe 1 mL Luer-Lok™ Tip is Polycarbonate)
Plunger rod	Polypropylene
Stopper	Natural Rubber/ Synthetic Rubber/ Thermoplastic Elastomers
Lubricant	Medical grade silicone

As per extract from technical file TF000002 (SG) linked to CE certificate number CE 01487 related to product SKUs:302113, 302146:

Component	Material
Syringe Barrel	Polypropylene
Plunger	Polypropylene
Plunger (Breakable)	Polypropylene
Stopper	Isoprene-based rubber / SBR-based rubber
Lubricant	Medical Grade Silicone

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:

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 02 February 2024, 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 article and packaging with the Product Number as referenced above, in an individual concentration above 0.1% w/w.
Latex	Based on our ongoing data collection efforts and information received from our suppliers as per 02 February 2024, natural rubber latex and latex are not part of the material formulation for the packaging materials referenced above.
Bisphenol A	Based on our ongoing data collection efforts and information received from our suppliers as per 02 February 2024, BD has not identified any • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the packaging materials referenced above, in an individual concentration above 0.1% (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 this packaging materials. **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 this device 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 22442-1:2020 and Section 6 of EMA 410/01 Rev. 3. Therefore,

Material	Comment
	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).
Polyvinyl chloride (PVC)	Based on our ongoing data collection efforts and information received from our suppliers as per 02 February 2024, the above referenced packaging materials have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC.

1.8 REACH information

Based on our ongoing data collection efforts and information received from our suppliers as per 02 February 2024, BD has not identified any chemicals in the packaging materials 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 14 June 2023 according to Art. 59 (1,10) of the Regulation (EC) No 1907/2006 (REACH).

1.9 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices. 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 (SKUs: 303174, 303173, 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® hypodermic Syringes without needle (SKUs: 302830, 309653, 309628, 309658, 309649, 300912, 302832, 309620) are sterilized in its final packaging configuration via an irradiation sterilization process (appropriate, validated method)

BD® hypodermic Syringes without needle (SKUs: 302146, 302113) are then sterilized using Cobalt 60 irradiation or gaseous Ethylene Oxide.

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. The product SKUs listed in this TDS have a shelf life of 5 years.

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.

Note:

- Shelf life: Processing by the user, such as re-sterilization, might impact the shelf life of the product.
- 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
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
UNE-EN 556-1 :2001 + AC :2006	Sterilization of medical devices - Requirements for medical devices to be labelled sterile
EN 1707 :1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings
EN ISO 10993 series	Part 1: 2009/ AC :2010 Evaluation and testing within a risk management process Part 7: 2008 / AC :2009 / Amd1:2019 Ethylene oxide sterilization residuals Part 18: 2009 Chemical characterization of materials
UNE-EN ISO 11737	Sterilization of medical devices – Microbiological methods Part 2: 2019 Tests of sterility performed in the definition, validation and maintenance 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, labeling and information to be supplied Part 1: General requirements
EN ISO 7864: 2016	Sterile hypodermic needles for single-use.
EN ISO 7886-1 :2018	Sterile hypodermic syringe 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 10993 series	Biological evaluation of medical devices. Part 2: 2007 Animal welfare requirements. Part 10: 2013. Tests for irritation and skin sensitization.
EN 1041 :2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11138-2:2017	Sterilization of health care products. Biological indicators. Biological indicators for ethylene oxide sterilization processes.
EN ISO 11607:2020	Packaging for terminally sterilized medical devices. Part 1: 2020 Requirements for materials, sterile barrier systems and packaging systems. Part 2: 2020 Validation requirements for forming, sealing and assembly processes.
UNE-EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods Part 1:2018 Determination of a population of microorganisms on products.
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.

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As per extract from the Technical Documentation for **Plastipak™ Syringes** on the Technical File (IT-004) and on 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, 303174.**

Standard reference number	Title
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
UNE-EN 556-1 :2001 + AC :2006	Sterilization of medical devices - Requirements for medical devices to be labelled sterile
EN 1707 :1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings
EN ISO 10993 series	Part 1: 2009/ AC :2010 Evaluation and testing within a risk management process Part 7: 2008 / AC :2009 / Amd1:2019 Ethylene oxide sterilization residuals Part 18: 2009 Chemical characterization of materials
UNE-EN ISO 11737	Sterilization of medical devices – Microbiological methods Part 2: 2019 Tests of sterility performed in the definition, validation and maintenance 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, labeling and information to be supplied. Part 1: General requirements
EN ISO 7886-1 :2018	Sterile hypodermic syringe 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 10993 series	Biological evaluation of medical devices. Part 2: 2007 Animal welfare requirements. Part 10: 2013. Tests for irritation and skin sensitization.
EN 1041 :2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11138-2:2017	Sterilization of health care products. Biological indicators. Biological indicators for ethylene oxide sterilization processes.
EN ISO 11607:2020	Packaging for terminally sterilized medical devices. Part 1: 2020 Requirements for materials, sterile barrier systems and packaging systems. Part 2: 2020 Validation requirements for forming, sealing and assembly processes.
UNE-EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods Part 1:2018 Determination of a population of microorganisms on products.
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.

As per extract from the Technical Documentation for the **BD® hypodermic 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
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019*	Medical devices – Application of Risk Management to Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices

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Standard reference number	Title
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 7886-1:2017*	Sterile hypodermic syringes for single-use – Part 1: Syringes for manual use
ISO 7886-2:1996*	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps
EN 556-1: 2001/AC: 2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Requirements for terminally sterilized medical devices
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 1707:1996*	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Lock Fittings
EN 8537:2007*	Sterile single-use syringes, with or without needle, for insulin
ISO 7864:1993*	Sterile hypodermic needles for single-use – Requirements and test methods
ISO 9626: 1991 AMD1 2001*	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
ISO 6009:2016*	Hypodermic needles for single-use – Colour coding for identification
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 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 – Establishing the sterilization dose
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
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 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 14155:2020*	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
IEC 62366-1: 2015+AMD2020	Medical devices – Part 1: Application of usability engineering to medical devices – Amendment 1
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
EN ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2:2006	Biological evaluation of medical devices Part 2: Animal welfare requirements

Standard reference number	Title
EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Test for local effects after implantation
EN ISO 10993-7: 2008/AC: 2009	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-9:2009	Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices Part 12: Sample preparation and reference materials
EN ISO 10993-13:2010	Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-14: 2009	Biological evaluation of medical devices Part 14: Identification and quantification of degradation products from ceramics
EN ISO 10993-15:2009	Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-16:2017	Biological evaluation of medical devices Part 16: Identification and quantification of degradation products from metals and alloys
EN ISO 10993-17:2009	Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation

*with exceptions

As per extract from the Technical Documentation for the **BD® hypodermic 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: 302113, 302146.**

Standard reference number	Title
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
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, labeling and information to be supplied. Part 1: General requirements
EN 1041 :2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607:2020	Packaging for terminally sterilized medical devices. Part 1: 2020 Requirements for materials, sterile barrier systems and packaging systems. Part 2: 2020 Validation requirements for forming, sealing and assembly processes.
UNE-EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods

Standard reference number	Title
	Part 1:2018 Determination of a population of microorganisms on products.
EN ISO 10993-1 :2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
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
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
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 14971:2019	Medical devices. Application of risk management to medical devices.
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 7886-1:1993/COR1: 1995	Sterile hypodermic syringes for single-use – Part 1: Syringes for manual use
ISO 7886-2 :1996	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps (applicable for Plastipak™ Luer-Lock)

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.

1.13 Classification

CE certificate number	BD Catalog number	Classification
2000 06 0273 CP	303174, 303173, 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.
95 06 0005 CP	305959, 301189 300629, 301229 300865, 300869	**Plastipak™ and Perfusion Syringes** are Class IIa under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.
252.231	302830, 302832, 309653, 309620, 309628, 309649, 309658, 300912	**BD® hypodermic syringes without needles** are Class I sterile or non-sterile with a measuring function, under Rule 1 of Annex IX of the Medical Devices Directive 93/42/EEC as amended. Rule 1 state: "All non-invasive devices are in Class one unless one of the rules set out hereinafter applies". Subsequent rules do not apply.
CE 01487	302113, 302146	**BD® hypodermic syringes without needles sterile** are Class I sterile and measuring (Is/Im), under Rule 1 of Annex IX of the Medical Devices Directive 93/42/EEC as amended: non-invasive device, to which exception do not apply.

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	CE certificate number	GMDN
303174, 303173, 303172, 300866, 301231, 300613, 301183, 300867, 300605	2000 06 0273 CP	**GMDN Code**: 47017 **GMDN Term**: General Purpose Syringe, single-use
305959, 301189, 300629, 301229, 300865, 300869	95 06 0005 CP	
302830, 302832, 309653, 309620, 309628, 309649, 309658, 300912	252.231	**GMDN Code**: 47017 **GMDN Term**: General Purpose Syringe, single-use **GMDN Code**: 35904 **GMDN Term:** Metered Delivery Hypodermic Syringe
302113, 302146	CE 01487	**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.

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*
303172	Plastipak™ Syringe 1 mL Luer SP120 (Packaging units)	1	120	960	No
303173	Plastipak™ Syringe 1 mL Luer Insulin U-40 SP120 (Packaging units)	1	120	960	No
303174	Plastipak™ Syringe 1 mL Luer without needle U-100 SP120 (Packaging units)	1	120	960	No
300866	Plastipak™ Syringe 50 mL Luer-Slip	1	60	240	No
301231	Plastipak™ Syringe 30 mL Luer-Slip	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
300867	Plastipak™ Syringe 50 mL Catheter Tip	1	60	240	No
300605	Plastipak™ Syringe 100 mL CT	1	50	100	No
305959	Plastipak™ Syringe 10 mL Luer-Lok™	1	100	400	No
301189	Plastipak™ Syringe 20 mL Luer-Lok	1	60	480	No
300629	Plastipak™ Syringe 20 mL Luer-Lok	1	120	480	No
301229	Plastipak™ Syringe 30 mL Luer-Lok	1	60	240	No
300865	Plastipak™ Syringe 50 mL Luer-Lok	1	60	240	No
300869	Plastipak™ Syringe 50 mL Luer-Lok Amber	1	60	240	No
302830	BD® Syringe 20 mL LL (48 per box)	1	48	192	No
302832	BD® Syringe 30 mL Luer-Lok (56 per box)	1	56	224	No
309653	BD® Syringe 50 mL Luer-Lok	1	40	160	No
309620	BD® Syringe 50 mL	1	40	160	No
309628	BD® Syringe 1 mL LL w/o DN (without Detached Needle)	1	100	800	Yes
309649	BD® Syringe 5 mL LL EURO 125 S/C (125 units per Shelf Carton)	1	125	500	Yes

BD Catalog number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
309658	BD® Syringe 3 mL LL EURO 200 S/C (200 units per Shelf Carton)	1	200	800	Yes
300912	BD® Syringe 10 mL (only[1]) Eurographics	1	100	400	Yes
302113	BD® Syringe 3 mL Luer-Lok™ Tip	1	100	800	No
302146	BD® Syringe 10 mL Eccentric Tip	1	100	400	No

[1] « Only » indicates that the SKU is a syringe only, not a syringe/needle combo product

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

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: 303174 303173 303172, 300866, 301231, 300613, 301183, 300867, 300605:

Component	Material
Printed paper	Medical grade paper
Bottom web (Film)	Polyamide/Polyethylene
Case 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
Unit Package/blister	All film perforated blister Top Web – Polypropylene Bottom Web – Polypropylene
Shelf Package	Corrugated carton
Case Carton	Corrugated carton

As per extract from technical file TF000002 (SG) linked to CE certificate number CE 01487 related to product SKUs: 302113, 302146:

Component	Material
Unit Package/blister	All film perforated blister Top Web – Medical Grade Paper Bottom Web – Nylon Film
Shelf Carton Package	Corrugated Paper Pulp
Case Package	Polyethylene Shrink-wrap Film
Labels	Paper with Dry Adhesive

2.3 Recycled material in packaging

BD Product Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
309658	Unknown	NA
309649	Unknown	NA
300912	Unknown	NA
309653	Unknown	NA
302830	61%	NA
302832	61%	NA
309620	Unknown	100%
302113	Unknown	NA
302146	70%	NA
300869	84%	NA
305959	0%	NA
303172	100%	NA
303173	100%	NA
303174	100%	NA
301189	84%	NA
301183	84%	NA
300605	100%	100%
300613	84%	NA
300629	84%	NA
301231	84%	NA
301229	84%	NA
300866	84%	NA
300867	84%	NA
300865	84%	NA
309628	Unknown	Unknown

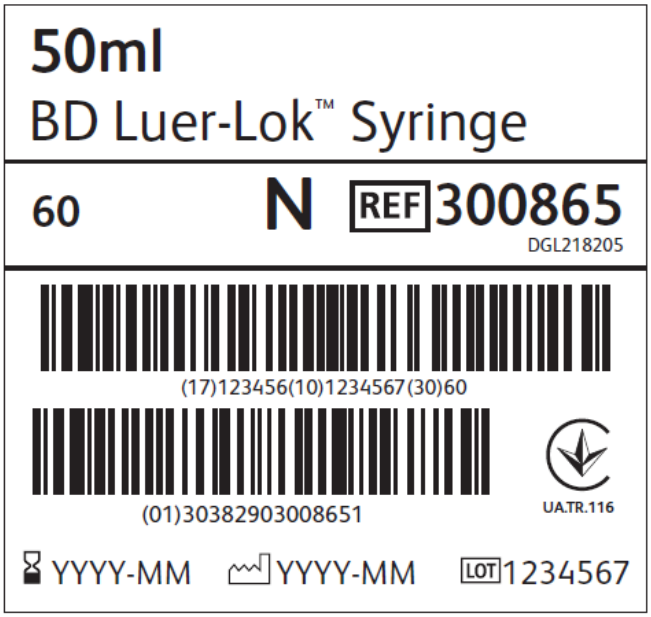
2.4 Examples of labeling

According to European Medical Device directive, labels are multilingual.

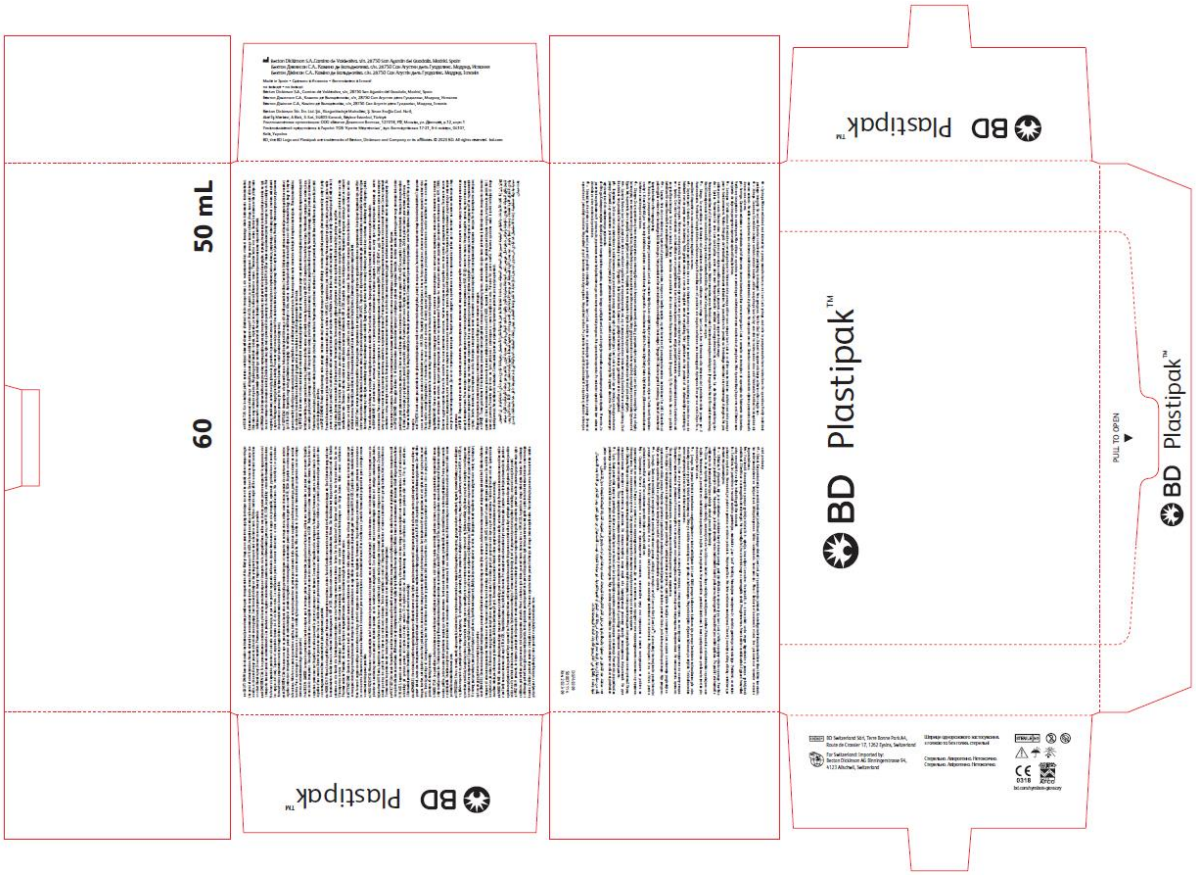
Labeling for Plastipak™ 50ml Luer Lok Syringe (SKU: 300865)

Unit Label extracted from document DGW1084 related to reference 300865:

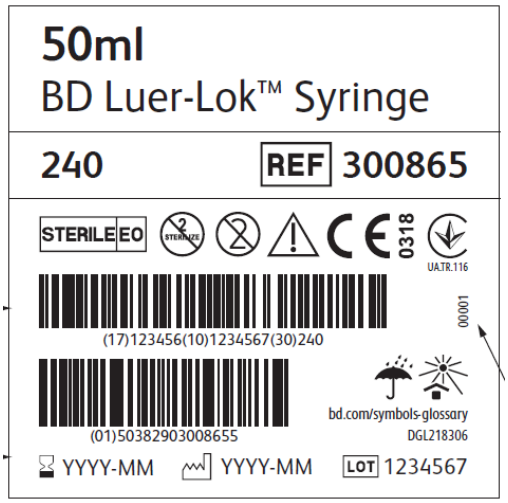
Shelf Label extracted from document DGL2182 related to reference 300865:



Shelf Carton extracted from document DGF403 related to reference 300865:



Case label extracted from document DGL2183 related to reference 300865:



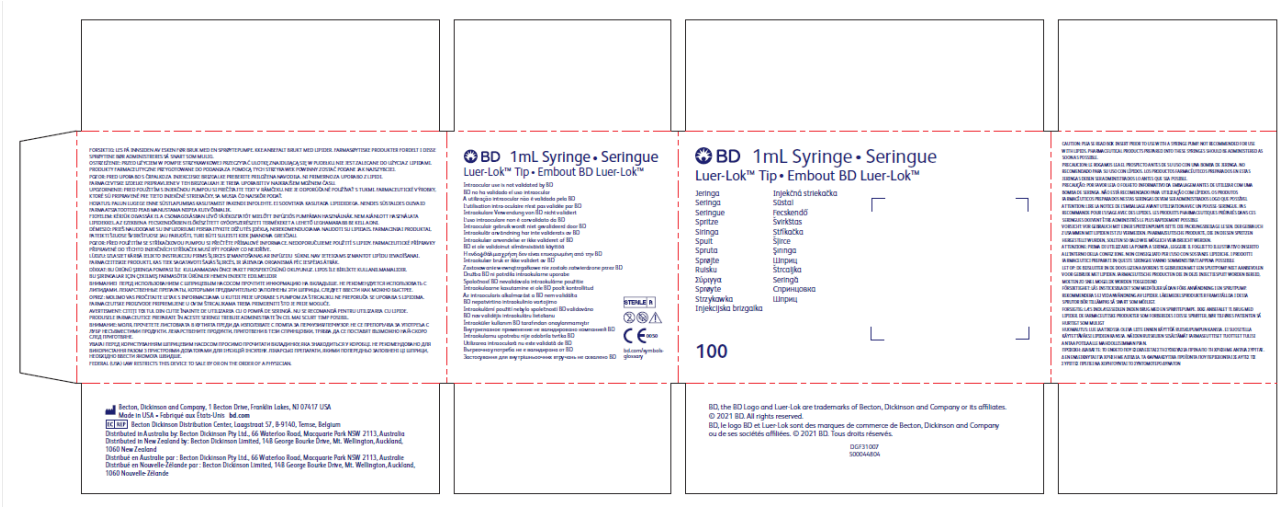
Labeling for BD® hypodermic 1 mL LL Syringe w/o DN (SKU: 309628):

Unit Label extracted from document DGW757 related to reference 309628:

Shelf Label extracted from document DGL1437 related to reference 309628:

Document Number: EMEA-SOP039-F1	**Rev. Lev.:** 01
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

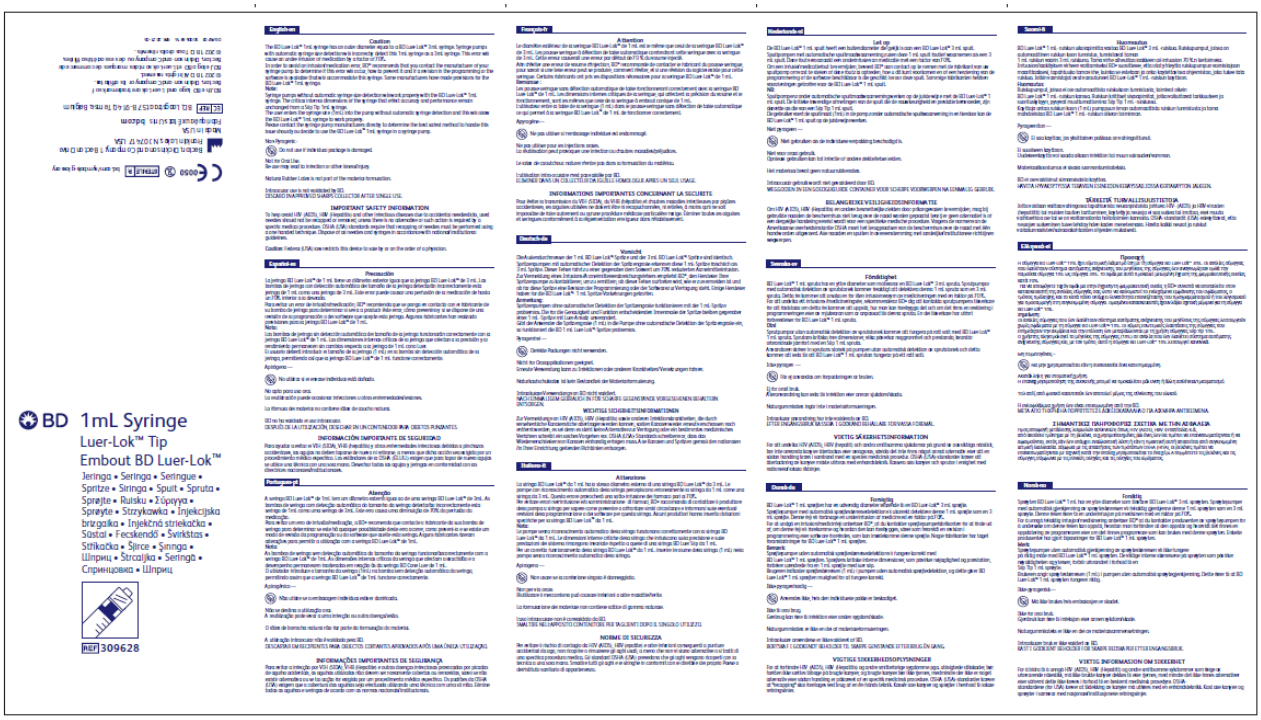
Shelf Carton extracted from document DGF310 related to reference 309628:



Case Label extracted from document DGL2232 related to reference 309628:

Document Number: EMEA-SOP039-F1	**Rev. Lev.:** 01
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

IFU insert extracted from document DGP67 related to reference 309628:



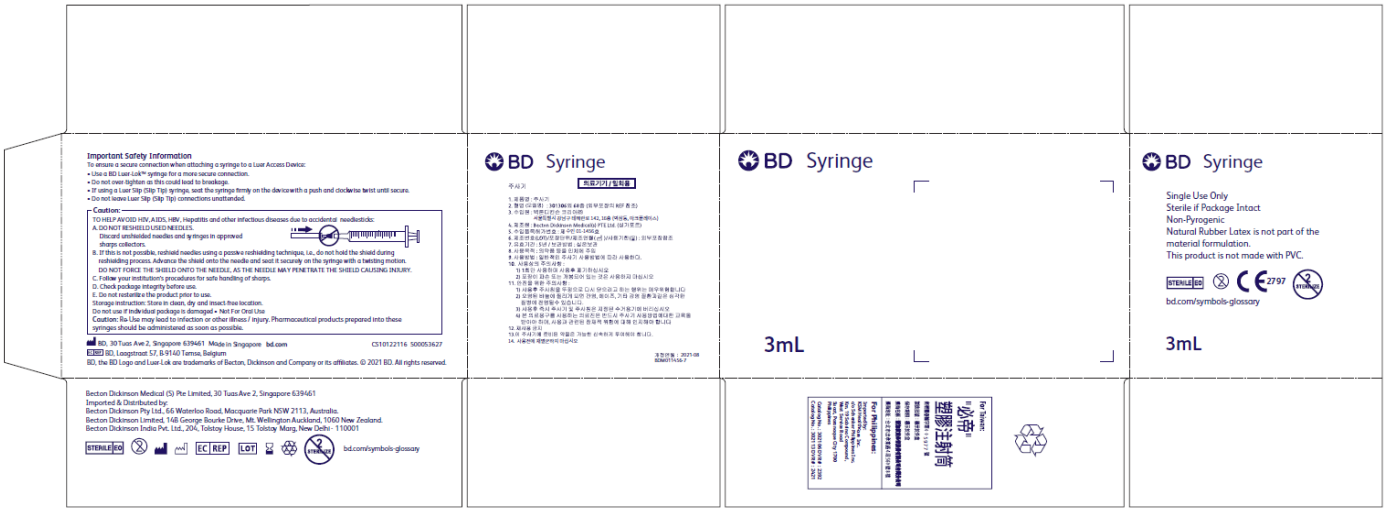
Labeling for BD® hypodermic 3ml Syringe Luer Lok™ Tip (SKU: 302113)

Unit Label extracted from document WS100730 related to reference 302113:

Document Number: EMEA-SOP039-F1	**Rev. Lev.:** 01
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

Shelf Label extracted from document SDGL26 related to reference 302113:

Shelf Carton extracted from document CS101221 related to reference 302113:



Document Number: EMEA-SOP039-F1	**Rev. Lev.:** 01
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

Case Label extracted from document SDGL27 related to reference 302113:

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