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

BD® Emerald™ Syringes without needle
Sterile, Single-use
Product codes: 307727 – 307731 – 307736 – 303219

BD® Emerald™ Syringes with BD Microlance™ 3 needle
Sterile, Single-use
Product codes: 303119 – 307728 – 307730 – 307732
307733 – 307737 – 307739 – 307742

BD® Emerald™ Syringes with BD® Blunt Fill needle
Sterile, Single-use
Product codes: 303221

Becton Dickinson S.A.
Carretera de Mequinenza s/n
22520 Fraga (Huesca), Spain

TDS number: V201-005 – Rev. 06
Veeva Vault Number: BD-139882
2024-December

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1. General Information

1.1 Intended purpose

BD® Emerald™ Syringes without needle (SKUs: 307727, 307731, 307736, 303219,) are a single-use medical device intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines.

BD® Emerald™ Syringes with BD Microlance™ 3 needle (SKUs: 303119, 307728, 307730, 307732, 307733, 307737, 307739 and 307742) are medical devices for single use intended for injection and/or aspiration of medical fluids, such as body fluids (blood) and medicinal substances.

BD® Emerald™ Syringes with BD® Blunt Fill needle (SKU: 303221) are a medical device for single-use intended drug loading and not for skin injection.

1.2 Intended User

The **BD® Emerald™ Syringes with or without BD needles** are intended to be used by medical practitioners (e.g. physicians, nurses, pharmacists) experienced in the use of the device. Experience levels will be from novice to expert.

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1.3 General Medical Devices description

BD® Emerald™ Syringes without needle are comprised of three plastic parts called plunger, stopper and cylinder. The stopper is green.

BD® Emerald™ Syringes with BD Microlance™ 3 needle and **BD® Emerald™ Syringes with BD® Blunt Fill needle** are joined by three plastic pieces (plunger, stopper and barrel) and needle. Stopper is Green

General features are as follows:

- BD® Emerald™ syringes demonstrate smooth plunger movement due to a low frictional force design and a silicone lubricated stopper.
- BD® Emerald™ syringes have up to 30% less material than similar syringes.
- Retaining ring designed to minimize accidental plunger rod pullout (1).
- Textured thumb press reduces flip page during administration (2).
- Manufactured with sterile barrier packaging to a Sterility Assurance Level (SAL) of 10-6 (3).

(1) , (2) BD Data on file, Emerald Conventional Syringe Claims Accuracy R&D Memo, June 30, 2021.
(3) From Veeva code: SFG 111: Syringe, 3 piece, BD Emerald, Single Use, Sterile (with or without needles) and Non-Sterile (v0.1).



Figures 1 and 2: BD® Emerald™ Syringes with Needles

BD Catalog Number	BD Product Description	Capacity	Scale	Tip	Gauge Size	Color Code	Length	Wall	Bevel
BD® Emerald™ syringes without needle									
307727	BD® Emerald™ syringe 2ml without needle	2 mL	0.1 mL	Luer-Slip Tip™ concentric	N/A	N/A	N/A	N/A	N/A
307731	BD® Emerald™ syringe 5ml without needle	5 mL	0.2 mL	Luer-Slip Tip™ concentric	N/A	N/A	N/A	N/A	N/A
307736	BD® Emerald™ syringe 10ml without needle	10 mL	0.2 mL	Luer-Slip Tip™ concentric	N/A	N/A	N/A	N/A	N/A
303219	BD® Emerald™ syringe 10ml without needle	10 mL	0.2 mL	Luer-Slip Tip™ eccentric	N/A	N/A	N/A	N/A	N/A

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BD Catalog Number	BD Product Description	Capacity	Scale	Tip	Gauge Size	Color Code	Length	Wall	Bevel
BD® Emerald™ syringes with BD® Blunt Fill needle									
303221*	BD® Emerald™ syringe 2ml with attached BD® Blunt Fill needle 18G × 1½" (1.2 × 40 mm)	2 mL	0.1 mL	Luer-Slip Tip™ concentric	18G	Red	1 ½" 40 mm	Thin	Blunt
BD® Emerald™ syringes with BD Microlance™ 3 needle									
303119	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	2 mL	0.1 mL	Luer-Slip Tip™ concentric	21G	Green	1 ½" 40 mm	Thin	Regular
307732*	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	5 mL	0.2 mL	Luer-Slip Tip™ concentric	21G	Green	1 ½" 40 mm	Thin	Regular
307737*	BD® Emerald™ syringe 10ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	10 mL	0.2 mL	Luer-Slip Tip™ concentric	21G	Green	1 ½" 40 mm	Thin	Regular
307739	BD® Emerald™ syringe 10ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	10 mL	0.2 mL	Luer-Slip Tip™ concentric	21G	Green	1 ½" 40 mm	Thin	Regular
307742	BD® Emerald™ syringe 5ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	5 mL	0.2 mL	Luer-Slip Tip™ concentric	21G	Green	1 ½" 40 mm	Thin	Regular
307728*	BD® Emerald™ syringe 2ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	2 mL	0.1 mL	Luer-Slip Tip™ concentric	22G	Black	1 ¼" 30 mm	Thin	Regular
307733*	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	5 mL	0.2 mL	Luer-Slip Tip™ concentric	22G	Black	1 ¼" 30 mm	Thin	Regular
307730*	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 23G × 1¼" (0.6 × 30 mm)	2 mL	0.1 mL	Luer-Slip Tip™ concentric	23G	Blue	1 ¼" 30 mm	Thin	Regular

*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 products SKUs 307728, 307730, 307732, 307733, 307737 and 303221 are no longer manufactured. For more information on the end date of the sales in your country, please contact your BD sales representative.

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These products (except SKU 307730) have been replaced by alternatives, as described in the table below. These are direct replacements with the same intended use.

Discontinued code	Discontinued code description	Substitute code	Substitute code Description
307728	BD® Emerald™ syringe 2ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	303119	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)
307730	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 23G × 1¼" (0.6 × 30 mm)	N/A	N/A
307732	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	307742	BD® Emerald™ syringe 5ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)
307733	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	307742	BD® Emerald™ syringe 5ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)
307737	BD® Emerald™ syringe 10ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	307739	BD® Emerald™ syringe 10ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)
303221	BD® Emerald™ syringe 2ml with attached BD® Blunt Fill needle 18G × 1½" (1.2 × 40 mm)	307727	BD® Emerald™ syringe 2ml without needle
		303129	BD® Blunt Fill needle 18G × 1½" (1.2 × 40 mm)

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)
307727 307731 307736 303219 303221	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	CE certified with AEMPS (0318) MDD Certificate No.: 2000 06 0272 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	N/A
303119 307728 307730 307732 307733 307737 307739 307742		CE certified with AEMPS (0318) MDD Certificate No.: 95 06 0006 CP		

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1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers referenced above 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 Documentation for **BD® Emerald™ syringes without needle** on the Technical File (DT-011):

	Component	Material
Syringe	Plunger	Polypropylene
	Barrel	Polypropylene
	Stopper	Thermoplastic elastomer (TPE) resin + colorant
	Lubricant	Silicone for barrel / stopper

As per extract from the Technical Documentation for **BD® Emerald™ syringes with BD Microlance™ 3 needle and BD® Emerald™ syringes with Blunt® Fill needle** on the Technical File (DT-012):

	Component	Material
Syringe	Plunger	Polypropylene
	Barrel	Polypropylene
	Stopper	Thermoplastic elastomer (TPE) resin + colorant
	Lubricant	Silicone for barrel / stopper
Needle	Hub	Colored polypropylene
	Shield	Polypropylene + colorant
	Bonding Agent (Adhesive)	Epoxy resin
	Cannula	Stainless steel
	Lubricant	Silicone oil

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 11 June 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),

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Material	Comment
	• 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 as per 11 June 2024, 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 11 June 2024, 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). Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material used in the adhesive. 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. 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.

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1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 June 2024, BD has not identified any chemicals in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 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.

1.10 Sterilization method

The products listed in this TDS are sterilized using a gas mixture of Ethylene Oxide and CO2 (in the proportion 90:10). Sterilization process is validated according to EN ISO 11135 "Sterilization of healthcare products-Ethylene oxide-: Requirements for development, validation and routine control of a sterilization process for medical devices". ETO residues are within applicable regulations.

1.11 Shelf life and storage conditions

The products listed in this TDS, shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
The products listed in this TDS have a shelf life of 5 years.

Note:

- 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.

1.12 Applied Standards

As per extract from the Technical Documentation for **BD® Emerald™ syringes without needle** on the Technical File (DT-011) and on the Declaration of Conformity (EU_DoC_BD_Emerald_ w_o_Needle_Rev_12) linked to EC certificate number 2000 06 0272 CP for **SKUs: 307727, 307731, 307736 and 303219.**

Standard reference number	Title
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 ISO 10993 series	Biological evaluation of medical devices
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

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Standard reference number	Title
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 syringes for single use - Part 1: Syringes for manual use
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN ISO 11138-2:2017	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes
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 **BD® Emerald™ syringes with BD Microlance™ 3 needle** on the Technical File (DT-012) and on the Declaration of Conformity (EU_DoC_BD_Emerald_w_Needle_Rev_18) linked to EC certificate number 95 06 0006 CP for **SKUs: 303119, 307728, 307730, 307732, 307733, 307737, 307739 and 307742.**

Standard reference number	Title
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 ISO 10993 series	Biological evaluation of medical devices
EN ISO 11737-2:2019	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 13485:2016/AC:2016	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"
ISO 2859:2011	"Sampling procedures for Inspection by Attributes" - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 6009:2016	Sterile hypodermic needles for single-use. Identification color coding
EN ISO 7864:2016	Sterile hypodermic needles for single-use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN ISO 11138-2:2017	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes

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Standard reference number	Title
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes
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 **BD® Emerald™ syringes with BD® Blunt Fill needle** on the Technical File (DT-012) and on the Declaration of Conformity (DoC_BD_Emerald_w_Blunt_Fill_Needle_Rev_8) linked to EC certificate number 2000 06 0272 CP for **SKUs: 303221.**

Standard reference number	Title
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 ISO 10993 series	Biological evaluation of medical devices
EN ISO 11737-2:2019	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 13485:2016/AC:2016	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"
ISO 2859:2011	"Sampling procedures for Inspection by Attributes" - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 6009:2016	Sterile hypodermic needles for single-use. Identification color coding
EN ISO 7864:2016	Sterile hypodermic needles for single-use
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN ISO 11138-2:2017	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes

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Standard reference number	Title
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

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

BD® Emerald™ Syringes without needle (SKUs: 307727, 307731, 307736 and 303219) are classified as Class I sterile with a measuring function Medical Devices, under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC.

BD® Emerald™ Syringes with BD Microlance™ 3 needle (SKUs: 303119, 307728, 307730, 307732, 307733, 307737, 307739 and 307742) are classified as Class IIa Medical Devices under Rule 6 of Annex IX of the Medical Devices Directive 93/42/EEC.

BD® Emerald™ Syringes with BD® Blunt Fill needle (SKU: 303221) are classified as Class I sterile with a measuring function Medical Devices, under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC.

1.14 Medical Device Nomenclature

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

- GMDN Code: 47017
- GMDN Term: General purpose syringes, 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

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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**
BD® Emerald™ syringes without needle					
307727	BD® Emerald™ syringe 2ml without needle	1	100	3000	No
307731	BD® Emerald™ syringe 5ml without needle	1	100	2000	No
307736	BD® Emerald™ syringe 10ml without needle	1	100	1200	No
303219	BD® Emerald™ syringe 10ml without needle	1	100	1200	No
BD® Emerald™ syringes with BD® Blunt Fill needle					
303221*	BD® Emerald™ syringe 2ml with attached BD® Blunt Fill needle 18G × 1½" (1.2 × 40 mm)	1	100	2000	No
BD® Emerald™ syringes with BD Microlance™ 3 needle					
303119	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	1	100	3000	No
307732*	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	1	100	1500	No
307737*	BD® Emerald™ syringe 10ml with attached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	1	100	900	No
307739	BD® Emerald™ syringe 10ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	1	100	1200	No
307742	BD® Emerald™ syringe 5ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm)	1	100	2000	No
307728*	BD® Emerald™ syringe 2ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	1	100	2000	No

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BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A/Yes/No**
307733*	BD® Emerald™ syringe 5ml with attached BD Microlance™ 3 needle 22G × 1¼" (0.7 × 30 mm)	1	100	1500	No
307730*	BD® Emerald™ syringe 2ml with detached BD Microlance™ 3 needle 23G × 1¼" (0.6 × 30 mm)	1	100	3000	No

*Products that are no longer manufactured. For more information on the end date of the sales in your country, please contact your BD sales representative.

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

2.2 Packaging material

As per extract from the Technical Documentation for **BD® Emerald™ syringes without needle** on the Technical File (DT-011) and from the Technical Documentation for **BD® Emerald™ syringes with BD Microlance™ 3 needle and BD® Emerald™ syringes with Blunt® Fill needle** on the Technical File (DT-012):

Component	Material
Unit Pack	Paper: Medical use paper 60gr/m^2 Film: Polyamide/Polyethylene
Shelf Box	Carton
Shipping Case	Corrugated carton

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.

-Recycled Content:

BD Catalogue Number	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
303219	Unknown	Unknown
307727	Unknown	100%
307731	Unknown	100%
307736	Unknown	100%
303119	Unknown	100%
307728	Unknown	Unknown

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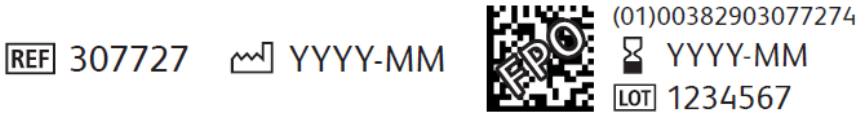
BD Catalogue Number	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
307730	Unknown	100%
307732	Unknown	Unknown
307733	Unknown	Unknown
307737	Unknown	Unknown
307739	Unknown	100%
307742	Unknown	100%
303221	Unknown	Unknown

2.4 Examples of labeling

According to European Medical Device directive, labels are multilingual.

Labeling for BD® Emerald™ Syringe 2ml without needle (SKU:307727):

Primary Packaging (Top Web) extracted from document DGW1037 (Rev.02) and 10000370649 (Rev.01) related to reference 307727:





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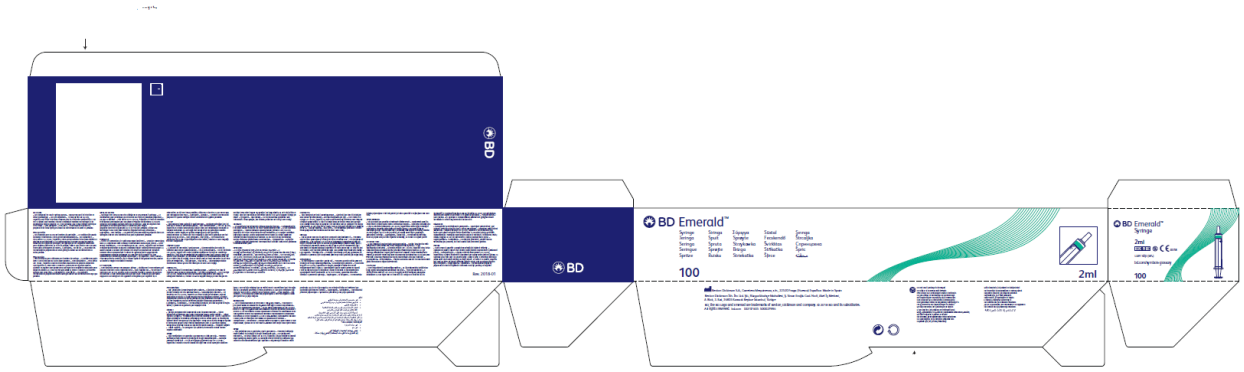
Shelf Box label extracted from document DGL1692 (Rev.01) related to reference 307727:

2ml

REF 307727

(01)30382903077275

Shelf Box extracted from document DGF376 (Rev.05) related to reference 307727:



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Shipping Case extracted from document DGC185 (Rev.02) related to reference 307727:



Case Label extracted from document DGL1782 (Rev.01) related to reference 307727:



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Labeling for BD® Emerald™ Syringe 2ml with detached BD Microlance™ 3 needle 21G × 1½" (0.8 × 40 mm) (SKU:303119):

Primary Packaging (Top Web) extracted from document DGW1659 (Rev.02) and 10000370649 (Rev.01) related to reference 303119:



Shelf Box label extracted from document DGL3069 (Rev.01) related to reference 303119:



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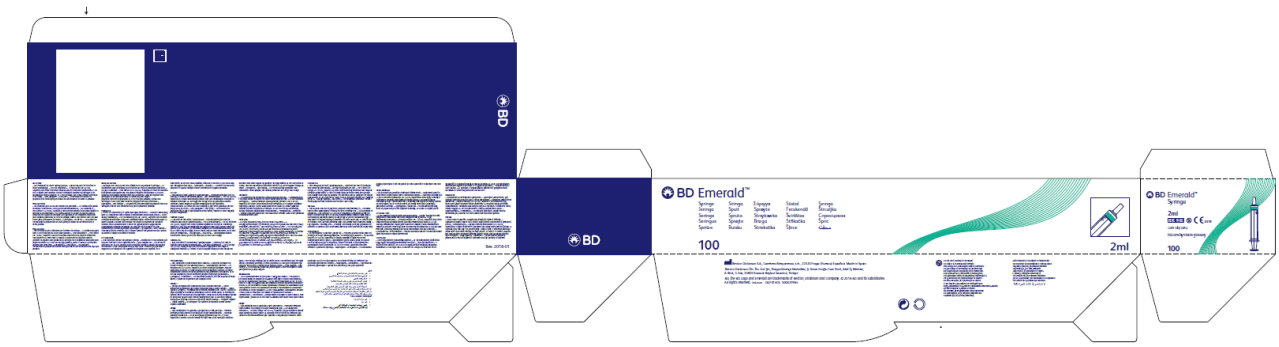
Shelf Box extracted from document DGF376 (Rev.05) related to reference 303119:



Shipping Case extracted from document DGC185 (Rev.02) related to reference 303119:



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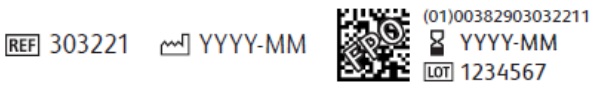
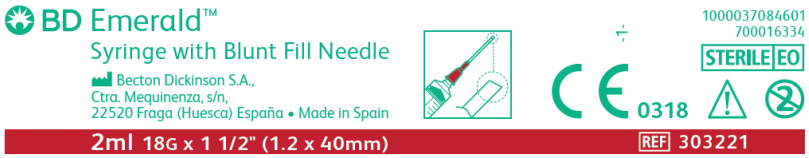
Case Label extracted from document DGL3071 (Rev.01) related to reference 303119:



Labeling for BD® Emerald™ syringe 2ml with attached BD® Blunt Fill needle 18G × 1½" (1.2 × 40 mm) (SKU: 303221):

Primary Packaging (Top Web) extracted from document 10000212109 (Rev.02) and 10000370846 (Rev.01) related to reference 303221:





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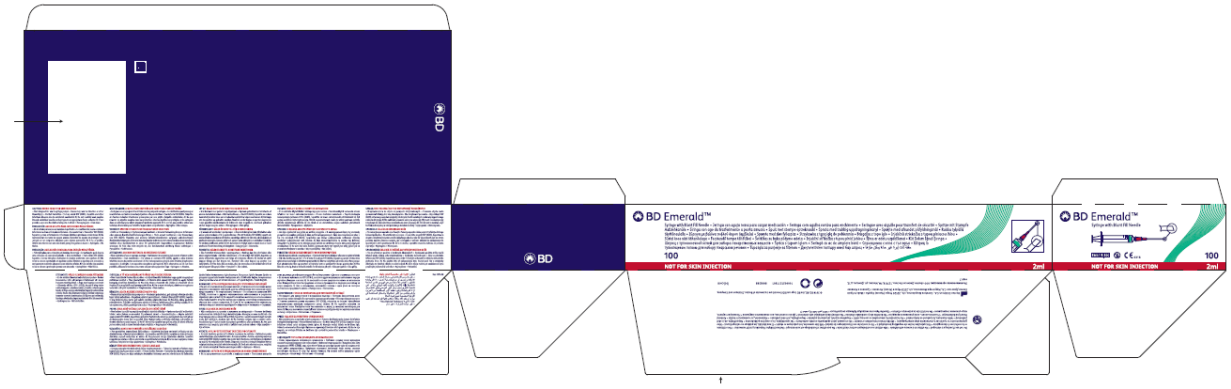
Shelf Box label extracted from document 10000212112 (Rev.01) related to reference 303221:



Shelf Box extracted from document 10000212118 (Rev.01) related to reference 303221:



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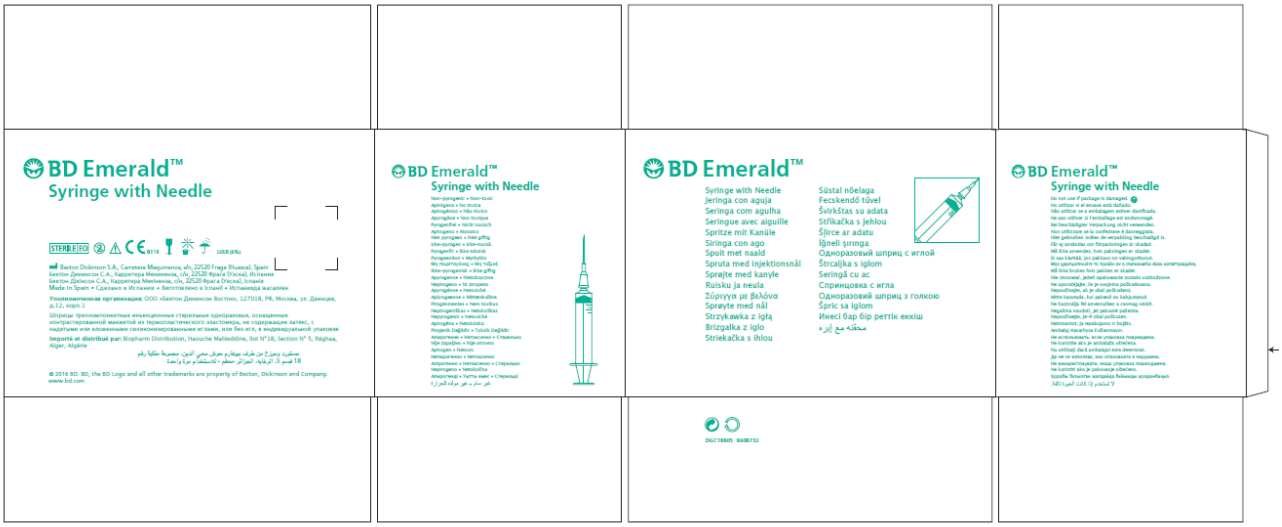
Shipping Case extracted from document DGC188 (Rev.05) related to reference 303221:



Case Label extracted from document 10000212115 (Rev.01) related to reference 303221:



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REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Adding of SKUs 303067 and 300846 Update of 1.3: Certification Update of 1.5: Materials of concern Update of 1.6: REACH information Update of 1.10: Standards
03	Removal of SKU 300846 Update of 1.10: Standards Update of 2.3: Examples of labelling
04	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 2.3 Examples of labeling Removal of SKUs 303124, 307734, 302909 and 302910 throughout the TDS because there are no sales in EU.
05	Release according to new template Discontinuation of SKUs 303079 (replaced by 307732), 302929 (replaced by 307737) 303111, 303112, 303113, 303114, 303115 and 303067. Update of: 1.2 General description 1.3 Certification 1.13 Standards 1.14 Classification 2.1 Packaging configuration 1.3 Certification: 303067 placed with the right Legal Manufacturer 1.8 Materials of concern: update as per technical file.
06	Remove the following product codes: 303032, 303034, 303044, 303047, 303048, 303049, 303109, 303111, 303112, 303113, 303114, 303115, 307729, 307735, 307738, 307740, 307741, 307743, 303139, 303067, 302986, 303140, 303079, 302929 Release according to new template: EMEA-SOP039-F1 as per technical files numbers: • DT-011, version 21 published on April 4th 2024 • DT-012, version 32 published on April 4th 2024

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