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Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

BD Emerald™ non-sterile three-piece Syringes in bulk

Bulk Non-Sterile, Single-use

Product codes: 303126 – 303127 - 303128

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

TDS number: V201-006 – Rev. 03
REF Veeva Vault: BD-116748
2024-February

1. General Information

1.1 Intended purpose

BD Emerald™ non-sterile three-piece Syringes in bulk (SKUs: 303126, 303127 and 303128) are a single-use medical devices intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines.

1.2 Intended User

BD Emerald™ non-sterile three-piece Syringes in bulk are intended for use by professional medical personnel in hospitals, clinics and medical centers. The end users are normally trained medical professionals or other users who are well trained and have experience in the use of these devices.

1.3 General Medical Devices description

BD Emerald™ non-sterile three-piece Syringes in bulk are comprised of three plastic parts called plunger, stopper, and cylinder. The stopper is green. After being assembled, the BD Emerald™ three-piece syringes are bulk non-sterile, single-use and are intended to be sterilized prior to use. These products are packaged in double plastic bags and shipment boxes (transport package).

Figure 1: BD Emerald™ syringe without needle

BD Catalog Number	BD Product Description	Capacity (mL)	Scale (mL)	Tip
303126	BD Emerald™ Syringe 2 ml in bulk	2	0.1	Luer Slip concentric
303127	BD Emerald™ Syringe 5 ml in bulk	5	0.2	Luer Slip concentric
303128	BD Emerald™ Syringe 10 ml in bulk	10	0.2	Luer Slip concentric

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)
303126 303127 303128	**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) Certificate No.: 99 03 0213 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	N/A

1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers referenced above 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 the requirement of MDR, it is still not available. The TDS will be updated once the transition to MDR is completed.

1.6 Materials

Component	Material
Plunger	Polypropylene
Stopper	Thermoplastic elastomer
Stopper colorant	Polyethylene (PE)-based green colorant
Barrel	Polypropylene
Scale printing	Printing foil
Lubricant	Polydimethylsiloxane

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.
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, 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

These catalogue numbers are sold non-sterile and are intended to be sterilized prior to use. They can be sterilized with ethylene oxide. Before sterilization, handling the product and opening the bag must be carried out in a controlled atmosphere.

Data to support sterilization of these products is available through contract arrangement with BD. The customer is responsible for the validation of the sterilization process and to assess the impact of the sterilization on the product.

1.11 Shelf life and storage conditions

BD Emerald™ non-sterile three-piece Syringes in bulk shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Emerald™ non-sterile three-piece Syringes in bulk have a shelf life of 5 years.

Note:
- Processing by the user, such as sterilization, might impact the shelf life of the non-sterile 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 **BD Emerald™ non-sterile three-piece Syringes in bulk** on the Technical File (DT-015) and on the Declaration of Conformity (EU_DoC_BD_Emerald_Bulk_Non-Sterile_Syringes_Rev_13) linked to CE certificate number 99 03 0213 CP, related to product **SKUs 303126, 303127 and 303128:**

Standard reference number	Title

93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
EN ISO 10993-1:2009	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
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 metals and alloys
EN ISO 10993-17:2009	Biological evaluation of medical devices — Part 17: Methods for the establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
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, labelling and information to be supplied - Part 1: General Requirements
ISO 2859-1:1999/Amd 1:2011	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 10993-2:2006	Biological evaluation of medical devices — Part 2: Animal welfare requirements
EN ISO 10993-4:2017	Biological evaluation of medical devices — Part 2: Animal welfare requirements
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-9:2019	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 10993-16:2017	Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
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™ non-sterile three-piece Syringes in bulk are Class I medical devices with a measuring function, as per Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC as amended.

1.14 Medical Device Nomenclature

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure)

For BD Emerald™ non-sterile three-piece Syringes in bulk:

- GMDN Code: 47017
- GMDN Term: General-purpose 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	Shipping Case (Qty)	Pallet (Qty)	IFU Insert N/A / Yes / No*
303126	BD Emerald™ Syringe 2 ml in bulk	5200	62400	No
303127	BD Emerald™ Syringe 5 ml in bulk	2700	32400	No
303128	BD Emerald™ Syringe 10 ml in bulk	1500	18000	No

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

2.2 Packaging material

Component	Material
Bag	Polyethylene double bagged
Shipping Case	Corrugated carton

2.3 Recycled material in packaging

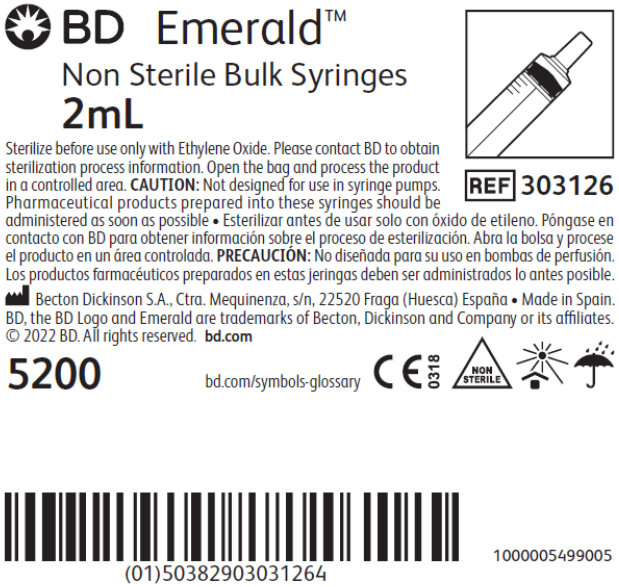
BD Product Number	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
303126	NA	Unknown
303127	NA	Unknown
303128	NA	Unknown

2.4 Examples of labeling

According to European Medical Device directive, labels are multilingual.

Labeling for BD Emerald™ Non Sterile Bulk Syringe 2ml in bulk (SKU: 303126)

Case Label extracted from document 10000054990 related to reference 303126:



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REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.2 General description Update of 1.4 Materials Update of 1.5 Materials of concern Update of 1.6 REACH information Update of 1.7 Biocompatibility Update of 1.8 Sterilization method Update of 1.9 Shelf life and storage conditions Update of 1.10 Standards Update of 1.11 Classification Update of 2.1 Packaging configuration Update of 2.3 Examples of labeling
03	Initial release according to new template EMEA-SOP039-F1 and version 10 of the Technical File DT-015 published on November 2nd, 2023