Becton Dickinson and Company
BD Medical,
Medication and Procedural Solution

BD Switzerland Sàrl
Terre Bonne Park - A4
Route de Crassier 17
1262 Eysins,
Switzerland

bd.com

TECHNICAL DATA SHEET

BD Emerald™ Syringe with and without needle
Sterile, Single Use, Latex free

1. General Information

1.1 General

The BD Emerald™ syringe is a medical single use product for injection and/or aspiration of medical fluids and drugs.

The 3-piece syringes BD Emerald™ are used with hypodermic needles, catheters, etc. For this purpose they are connected with the needle hub or catheter, in a manner that they remain perfectly fitted. Once the product has been used, the syringe must be discarded to avoid infection, preferably using the disposal containers available in the market.

The 3-piece BD Emerald™ syringe with needle is a medical device for single use intended for injection and/or aspiration of medical fluids, such as body fluids (blood) and medicinal substances.

The 3-piece BD Emerald™ syringe with Blunt Fill needle is a medical device for single use intended drug loading and not for skin injection.

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LUER SLIP SYRINGES WITHOUT NEEDLE

Reference	Capacity	Description	Scale Graduation	Box (units)	Case (units)
307727	2 ml	Central cone	0.1 ml	100	3000
302986	3 ml	Central cone	0.1ml	100	2400
307731	5 ml	Central cone	0.2 ml	100	2000
307736	10 ml	Central cone	0.2 ml	100	1200

LUER SLIP SYRINGES WITH PRE-ATTACHED NEEDLE (assembled)

Reference	Capacity	Description			Scale Graduation	Box (units)	Case (units)
		Syr. Cone	Gauge	Lenght			
307728	2 ml	Central	22G	1 ¼"	0.1 ml	100	2000
307740	2 ml	Central	23G	1"	0.1 ml	100	2000
307741	2 ml	Central	23G	1 ¼"	0.1 ml	100	2000
307732	5 ml	Central	21G	1 ½"	0.2 ml	100	1500
307733	5 ml	Central	22G	1 ¼"	0.2 ml	100	1500
307735	5 ml	Central	23G	1 ¼"	0.2 ml	100	1500
307737	10 ml	Central	21G	1 ½"	0.2 ml	100	900
307738	10 ml	Central	22G	1 ¼"	0.2 ml	100	900

LUER SLIP SYRINGES WITH PRE-ATTACHED BLUNT FILL NEEDLE (assembled)

Reference	Capacity	Description			Scale Graduation	Box (units)	Case (units)
		Syr. Cone	Gauge	Lenght			
303221	2 ml	Central	18G	1 ½"	0.1 ml	100	2000
303139	5 ml	Central	18G	1 ½"	0.2 ml	100	1500
303140	10 ml	Central	18G	1 ½"	0.2 ml	100	900

DEAD SPACE (maximum, without needle) (except for catheter tip syringes)

Syringe size	2ml	3 ml	5ml	10ml
Dead space	0.07ml	0.07 ml	0.075ml	0.10ml

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1.2 Certification

BD REFERENCE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
307727, 307731, 307736, 303221, 303139, 303140,	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain	AENOR - EN ISO 9001:2008 Certificate Nº N° ER-0097/1994 AEMPS NB nº0318 EN ISO 13485:2013 Certificate N° 2015 05 0047EN	AEMPS N°0318 – Certificate n 2000 06 0272 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain
302986	Becton Dickinson India (P) Ltd. Plot No 1, Sector 3, IMT, Bawal-123 501, District Rewari, Haryana, India	DNV EN ISO 9001:2008 Certificate Nº150540-2014-AQ-IND-NA EN ISO 13485:2012 Certificate Nº 150539-2014-AQ-IND-NA	DNV 0434 – Certificate n. 68879-2009-CE-IND-NA	Becton Dickinson India (P) Ltd. Plot No 1, Sector 3, IMT, Bawal-123 501, District Rewari, Haryana, India
307728, 307740, 307741, 307732, 307733, 307735, 307737, 307738	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain	AENOR - EN ISO 9001:2008 Certificate Nº N° ER-0097/1994 AEMPS NB nº0318 EN ISO 13485:2013 Certificate N° 2015 05 0047EN	AEMPS N°0318 – Certificate 95 06 0006 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain

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1.3 Material

COMPONENT	MATERIAL
Barrels, plunger rods	POLYPROPYLENE
Barrels, Stoppers	LATEX FREE ELASTOMER (TPE)
Barrels, Lubricant	SILICONE OIL, <0.25 mg/cm^2
NEEDLE	
Needle Hub	COLOR CODED POLYPROPYLENE
Needle Shield	POLYPROPYLENE
Bonding Agent	EPOXY
Needle	STAINLESS STEEL AISI 304 (Chromium 18-20%; Nickel 8-12%; Manganese 2%; Silicon 1%)
Lubricant	MEDICAL GRADE SILICONE, <0.25 mg/cm^2
Web packaging	POLYAMIDE
Box	SOFT PAPER

1.4 Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

MATERIAL	COMMENT
Phthalates	The products do not contain phthalates. No DEHP, CAS number 117-81-1, EC number 204-211-0, intentionally added
Latex	The products do not contain natural latex.
Bisphenol A	The products do not contain Bisphenol A.
Substances of animal origin BSE/TSE	The products were assessed for TSE (Transmissible Spongiform Encephalopathy) contamination risk. The raw materials used in the manufacture of this device do not contain any animal tissue but may contain very small amounts of animal derived raw materials. This product is manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow derived materials have been produced using multiple cycles of conditions at least as rigorous (and normally more rigorous) as those specified in Annex C.5 of EN ISO 22442-1. Therefore, the raw materials meet or exceed the requirements of EN ISO 22442-1. Therefore, the raw materials do not to present any risk with respect to TSE or other animal borne disease
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

1.5 REACH information

BD maintains an active REACH compliance program and works closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern (“SVHC”) through regular communication and exchange

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1.6 Biocompatibility

BD Medical products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.7 Sterilization

Ethylene Oxide Sterilization following *EN ISO 11135-1*. ETO residues are within applicable regulations.

1.8 Shelf life

Shelf life 5 years. No special storage or transportation condition. Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

1.9 Standards

Harmonised Standards	Title
EN 556:2001+AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE".
EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN 1422 :1997 + A1 :2009	Sterilizers for medical purposes – Ethylene oxide sterilizers – Requirements and test methods
EN ISO 9001 :2008+AC :2009	Quality System Management. Requirements
EN ISO 10993 series	Biological evaluation of medical devices
EN ISO 11135-1:2007	Sterilization of health-care products --.Ethylene oxide
EN ISO 11138:2009.	Sterilization of health care products. Biological indicators.
EN ISO 11607 • Part 1: 2009 • Part 2: 2006	Packaging for terminally sterilized medical devices
EN ISO 11737	Sterilization of medical devices – Microbiological methods
EN ISO 13485:2012 / AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN 20594-1: 1993/ A1:1997 / AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.

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Non-Harmonised Standards	Title
ISO 2859-1 :1999 + Cor.1 : 2001 + Amd.1 :2011	Sampling procedures for Inspection by Attributes
EN ISO 6009 :1996	Sterile hypodermic needles for single use. Identification color coding
EN ISO 7864 : 1995	Sterile hypodermic needles for single use.
EN ISO 7886-1 :1997	Sterile hypodermic syringe for single use. Part 1: Syringes for manual use.
EN ISO 9626:1995/A1:2002	Stainless steel needle tubing for the manufacture of medical devices.
EN ISO 15223-1:2012	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 14644-1:1999	Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness
EN ISO 10993 series	Biological evaluation of medical devices. Part 10 : 2013. Tests for irritation and skin sensitization.

1.10 Classification

- BD Emerald™ with sterile needle, SKU 307728, 307740, 307741, 307732, 307733, 307735, 307737 and 307738, are classified as Medical Devices class IIa sterile with a measuring function classification rule 6 according to Medical Devices Directive 93/42/EEC.
- BD Emerald™ with blunt fill needle, SKU 303221, 303139 and 303140, are classified as Medical Devices class I sterile with a measuring function, classification rule 2 according to Medical Devices Directive 93/42/EEC.
- BD Emerald™ without needle, SKU 307727, 307731, 307736 and 302986, are classified as Medical Devices class I sterile with a measuring function, classification rule 2 according to Medical Devices Directive 93/42/EEC.

1.11 GMDN code

GMDN code 47017: General purpose syringes.

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1.12 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good 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.
- BD reserves the right to use the internal change control procedure to change raw material suppliers and production process

1.13 Others

- (Material) Safety Data Sheets are not required for this product
- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch 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.
- The EU representative for India produced syringe catalogue number 302986 is BD Temse, Belgium. Other syringes are produced by a European manufacturer.

2. Packaging

2.1 Packaging material

LABELS: according to European Medical Device directive, multilingual

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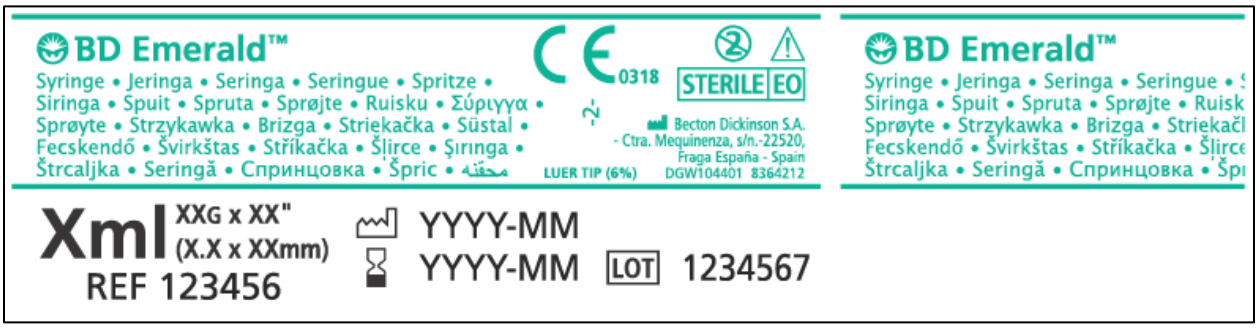
2.2 Example labeling

Unit pack label, Syringe only, from document DGW1044

Unit pack label, Syringe with pre-attached needle, from document DGW1044



Unit pack label, Syringe with Blunt fill needle, from document 10000212108