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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. Normally, 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.

Single use latex free sterile syringe, for injection and aspiration.

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

1.2 Technical details

DEAD SPACE (maximum, w/o needle) (except for catheter tip syringes)

SYRINGE SIZE	2ml	3 ml	5ml	10ml
Dead Space	0.07ml	0.07 ml	0.075ml	0.10ml

1.3 Certification

BD Product Code	BD Manufacturer	ISO Certification	CE Marking	BD Manufacturing Site
307727 307731 307736	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
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 n° 95 06 0006 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

1.4 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	SILICONE, <0.25 mg/cm^2
Web packaging	POLYAMIDE
Box	SOFT PAPER

1.5 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
DEHP/Phthalates	The products do not contain di(2ethylhexyl) phthalate DEHP as CAS number 117-81-7, EC number 204-211-0.
Latex	The products do not contain natural latex
Bisphenol A	For products attached to a needle, Bisphenol A (BPA) as CAS number 80-05-7, EC number 201-245-8, might be found in very low amount (at a concentration inferior to 5ppm) as a residue from the epoxy synthesis processing.
Substances of animal origin BSE/TSE	These devices utilize very small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Per MEDDEV 2.4/1 Rev. 9 June 2010 and Directive 2003/32/EC, such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.
Polyvinyl chloride	The product and its packaging does not contain polyvinyl chloride

1.6 REACH information

Based on information available and BD's continuous data collection efforts throughout the supply chain, BD have 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 28 October 2008, according to Art. 59 (1, 10) of the Regulation (EC) N° 1907/2006 (REACH). The substances published in such list are candidates for eventual inclusion in the List of Substances Subject to Authorization (Annex XIV of REACH).

1.7 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.

1.8 Sterilization

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

1.9 Shelf life

- Shelf life 5 years
- Store in dry and warm place and not exposed to strong light and then include any specific storage conditions if special handling is applicable

1.10 Standards

ALL SYRINGES MEET THE FOLLOWING STANDARDS:

- EN 556-1 Sterilization of Medical Devices-requirement for medical devices to be labeled "sterile"
- EN ISO 7864 Sterile hypodermic needles for single use
- EN 980 Graphical Symbols for use in the labeling of medical devices
- EN 1041 Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
- EN 1707 / ISO 594-2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Lock fittings (only applies to Luer Lock Syringes)
- EN ISO 7886-1 Sterile hypodermic syringes for single use
- EN 20594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirements (ISO 594-1:1986)
- EN ISO 6009 Hypodermic needles for single use -- Colour coding for identification
- EN ISO 9626 Stainless steel needle tubing for the manufacture of medical devices
- EN ISO 10993 series Biological evaluation of medical devices
- EN ISO 11135-1 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 11737-1 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- EN-ISO 11737-2 Sterilization of medical devices- Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- EN ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- EN ISO 13485 Medical Devices, Quality Management Systems, Requirements for Regulatory purposes
- EN ISO 14971 Medical devices- Application of risk management to medical devices
- EN ISO 15223-1 Medical devices-Symbols to be used with medical devices labels, labeling and information to be supplied Part.1: General requirements

1.11 Classification

Class IIa (syringes: 307727, 302986, 307731, 307736) Medical Device under Rule 6, Annex IX of Medical Devices Directive 93/42/EEC as amended.
Class I Sterile with a measuring function (syringes: 307728, 307740, 307741, 307732, 307733, 307735, 307737, 307738)) Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.

1.12 GMDN code

GMDN code is 47017: General purpose syringes

1.13 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

1.14 Others

- The EU representative for India produced syringe catalogue number 302986 is BD Temse, Belgium. Other syringes are produced by a European manufacturer.
- Material Data Safety 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.

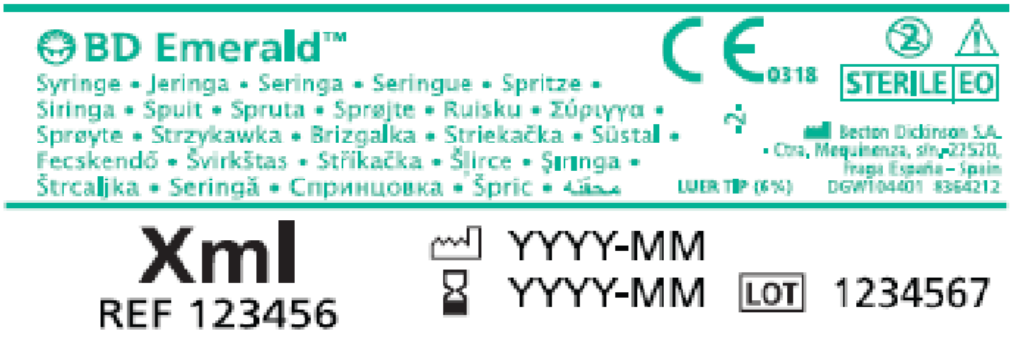
2. Packaging

2.1 Label information

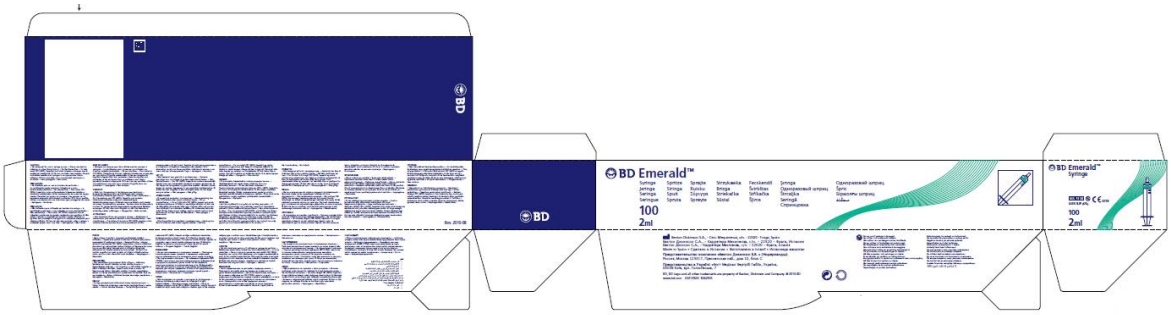
LABELS: According to European Medical Device directive, multilingual

2.2 Label Design

Unit pack



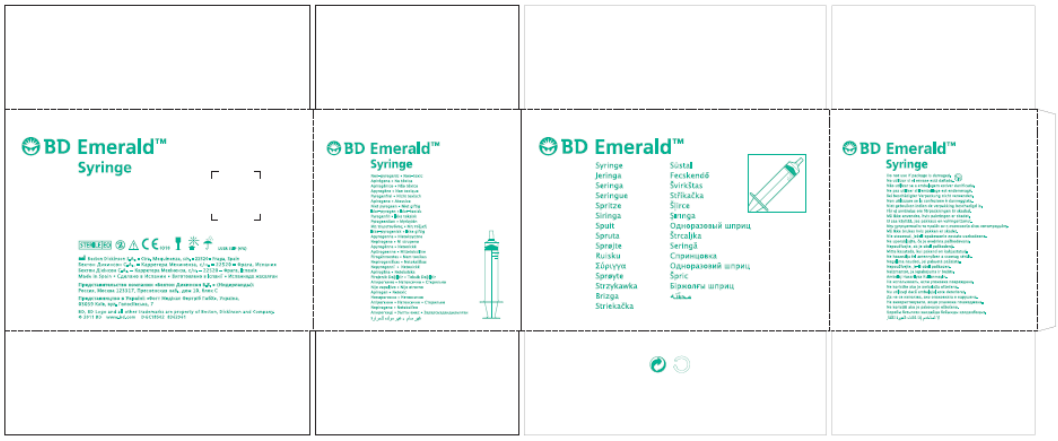
Shelf carton



Shelf carton label

Shipping case label

Shipping Case



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