BD Flu+ syringes with cannula, Sterile,

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-065 – Rev. 01
2019-July

1. General Information

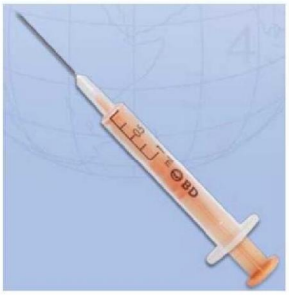
1.1 Intended use

BD Flu+ two-piece syringes with cannula are a single-use medical device intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines.

1.2 General description

Flu+ two-piece syringes consist of two plastic parts called plunger and cylinder. A metal part called cannula, with a beveled tip, is attached to the cylinder using epoxy resin bonding agent The external wall of the cannula is lubricated with silicone oil for perfect penetrability. The ensemble is protected with a plastic part called the protector.

Flu+ two-piece syringes with cannula are medical devices with pre-attached needle. They are not designed for connecting with other medical devices or equipment.



BD Catalog Number	BD Product Description	Volume (ml)	Gauge Size	Length (inch)	Length (mm)	Color Code
305832	SYRINGE FLU PLUS 0.25-1ML VAR DOSE 23X1	0.25-1	23	1"	25	Blue
305834	SYRINGE FLU PLUS 0.25-1ML VAR DOSE 25X1	0.25-1	25	1"	25	Orange
305836	SYRINGE FLU PLUS 0.25-1ML VARDOSE 25X5/8	0.25-1	25	5/8"	16	Orange

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 use the BD Catalog Number.

Further features: N/A

1.3 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)
305832 305834 305836	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0006 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	N/A

1.4 Materials

	Component	Material
Syringe	Plunger	Polyethylene + Colorant
	Barrel	Polypropylene
Needle	Shield	Polypropylene
	Cannula	Stainless steel
	Adhesive	Epoxy resin
	Lubricant	Silicone oil

1.5 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.

Material	Comment
Phthalates	The products do not contain phthalates
Latex	The products do not contain natural rubber latex.
Bisphenol A	The products do not contain polycarbonate, and therefore no Bisphenol A (BPA) as CAS number 80-05-7, EC number 201-245-8. Bisphenol A (BPA), CAS number 80-05-7, is a component in a raw material in the adhesive. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% wt/wt «1000 ppm).
Substances of animal origin BSE/TSE	The raw material used in manufacture of this medical device do not contain any animal tissue but may contain very small amounts of animal-derived raw materials. This product is manufactured using polymers resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow-derived have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN 22442-1 and section 6 of EMA 410/01. Therefore, these raw materials meet or exceed the requirements of EN 22442-1 and EMA 410/01. Based on this information, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases Furthermore, as recognized by MEDDEV 2.4/1, tallow processed in accordance with the aforementioned standards and guidelines is considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC). 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 the Directive 2003/32/CE, such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.

1.6 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging of BD Flu+, 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 27 June 2018 according to Art. 59 (1.10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 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.

1.8 Sterilization method

Ethylene oxide sterilization in accordance with EN ISO 11135-1 (*Sterilization of health care products - Ethylene oxide – Part1: Requirements for development, validation and routine control of a sterilization process for medical devices).*

1.9 Shelf life and storage conditions

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

Note:
BD recommend to store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity linked to CE certificate number 95 06 006 CP:

Harmonized Standards	
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 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993 Series	Biological evaluation of medical devices
EN ISO 11135-1:2007	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2009	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006 /AC:2009	Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products
EN ISO 11737-2:2009	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 14971:2012	Medical devices. Application of risk management to medical devices.
Non-Harmonized Standards	
EN ISO 6009:2016	Hypodermic needles for single use. Colour coding for identification
EN ISO 7886-1:1997	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 9626:1995 /A1:2001	Stainless steel needle tubing for the manufacture of 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.

1.11 Classification

The family of products called Flu+ two-piece syringes with cannula are Class IIa medical devices according to Rule 6 of Annex IX of Medical Devices Directive 93/42/EEC of 14 June 1993.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Flu+ are referenced as follows:
GMDN Code: 47017
GMDN Term: General-purpose syringes, single-use

1.13 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.

1.14 Other information

- (Material) 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 is 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*
305832	SYRINGE FLU PLUS 0.25-1ML VAR DOSE 23X1	1	200	2400	N/A
305834	SYRINGE FLU PLUS 0.25-1ML VAR DOSE 25X1	1	200	2400	N/A
305836	SYRINGE FLU PLUS 0.25-1ML VARDOSE 25X5/8	1	200	2400	N/A

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

2.2 Packaging material

Component	Material
Unit Pack	Polyamide/Polyethylene Medical use paper
Shelf Box	Carton
Shipping Case	Corrugated Carton

2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document DGW318 related to reference 305832:

Shelf Box extracted from document DGF172 related to reference 305832:

REVISION	CHANGE SUMMARY
01	Initial release according to new template