BD Discardit™ II syringes without needle, Sterile,
300928 – 309050 – 309110 - 300296

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TDS number: V201-003 – Rev. 01
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1. General Information

1.1 Intended use

BD Discardit™ II two-piece syringes 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

BD Discardit™ II two-piece syringes consist of two plastic parts called plunger and cylinder. After the BD Discardit™ II two-piece syringes are assembled they are packaged in single unit packages (primary package) and placed inside the unit cartons (secondary package). These cartons are protected by using shipment boxes (transport package). Afterwards, the BD Discardit™ II two-piece syringes are sterilised using Ethylene Oxide.

BD Catalog Number	BD Product Description	Capacity	Tip	Scale
300928	SYRINGE S2 2ML	2ml	Concentric	0.1ml
309050	SYRINGE S2 5ML	5ml	Eccentric	0.2ml
309110	SYRINGE S2 10ML	10ml	Eccentric	0.5ml
300296	SYRINGE S2 20ML	20ml	Eccentric	1ml

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the DoC, please always 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)
300928 309050 309110 300296	**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 AEMP (0318) Certificate No.: 2000 06 0272 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
Plunger	Polyethylene +white colorant
Barrel	Polyethylene, polypropylene

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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 March 2019, BD has not identified any • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis(2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • N-pentyl-isopentylphthalate (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% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 March 2019, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 March 2019, BD has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the articles with the Product Numbers as referenced above. 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 these products.
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 acids 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 22442-1 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, as recognized by MEDDEV 2.4/1, 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 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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 March 2019, BD has not identified any chemicals in the articles and packaging of BD Discardit™ II syringes without needle, 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

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

1.9 Shelf life and storage conditions

The BD Discardit™ II syringes shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Discardit™ II syringes without needle have a shelf life of 5 years.

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 the CE certificate number 2000 06 0272 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 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.
EN 20594-1:1993 /A1:1997/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN 1041:2008	Information supplied by the manufacturer of 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
Non-Harmonized Standards	
EN ISO 7886-1:1997	Sterile hypodermic syringes for single use. Syringes for manual use

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

Class I with measuring function Medical Device under Rule 2, Annex X of Medical Devices Directive 93/42/EEC as amended.

1.12 GMDN code

According to GMDN nomenclature, based on ISO 15225, BD Discardit™ II 2-pieces syringes are referenced as follows:

GMDN code: 47017

GMDN term: General-purpose syringe, single-use

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.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* 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 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	Pallet (Qty)	IFU Insert N/A / Yes / No*
300928	SYRINGE S2 2ML	1	100	3000	60000	N/A
309050	SYRINGE S2 5ML	1	100	1800	36000	N/A
309110	SYRINGE S2 10ML	1	100	1200	24000	N/A
300296	SYRINGE S2 20ML	1	80	960	19200	N/A

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

2.2 Packaging material

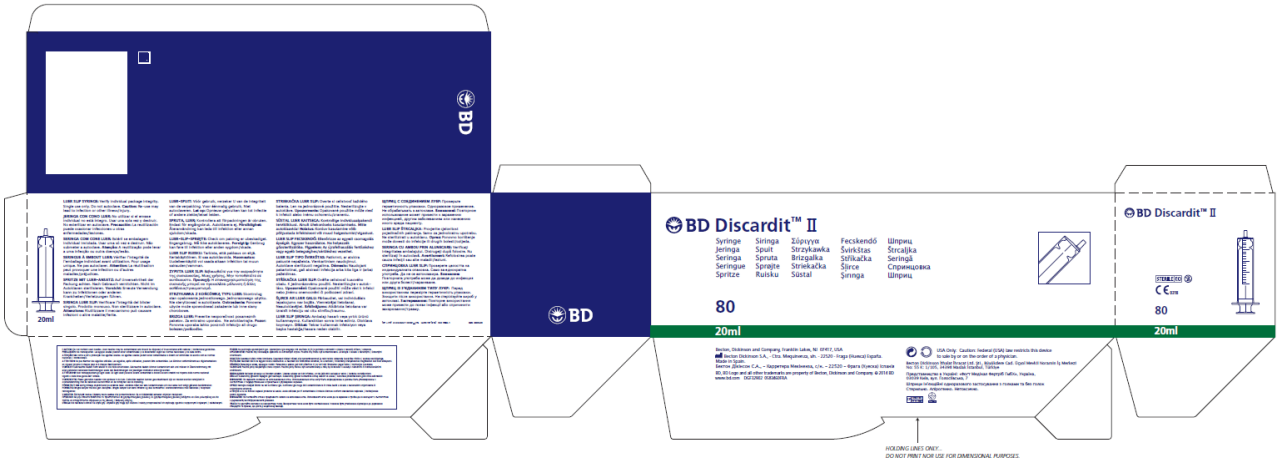
Component	Material
Unit Pack	Paper: Medical use paper Film: Polyamide/Polyethylene
Shelf Box	Carton
Shipping Case	Corrugated carton

2.3 Examples of labeling

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

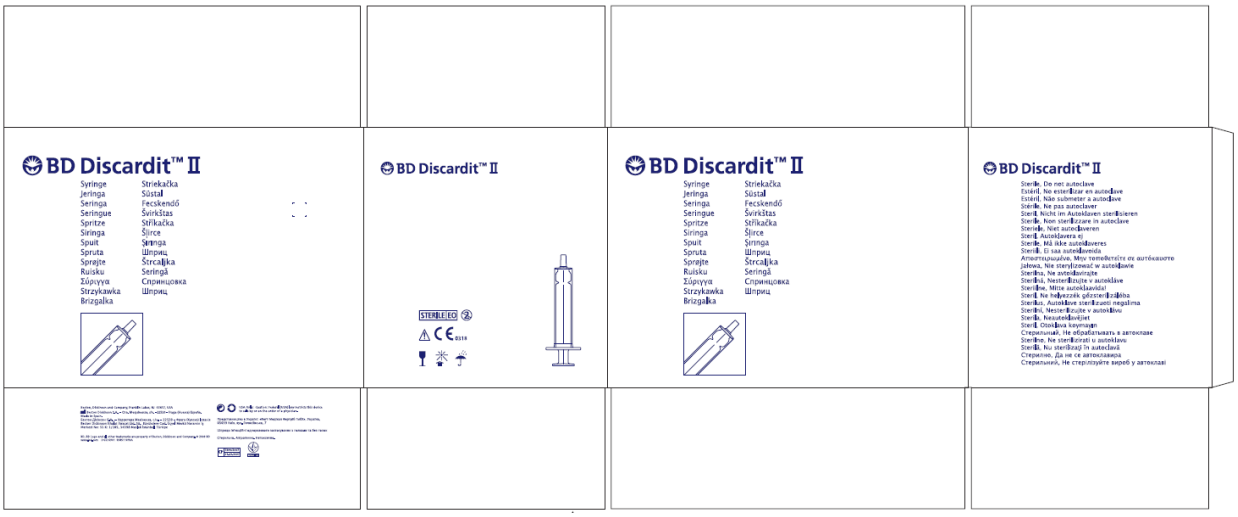
Primary Packaging Label (Top Web) extracted from document DGW889 related to reference 300296:

Shelf Box extracted from document DGF329 related to reference 300296:



Shelf Box label extracted from document EE-300296 related to reference 300296:

Shipping Case extracted from document DGC169 related to reference 300296:



Case Label extracted from document EE-300296 related to reference 300296:

REVISION	CHANGE SUMMARY
01	Initial release according to new template