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TECHNICAL DATA SHEET

BD Discardit™ II Syringe without needle
Sterile, Single use, Latex Free

1. General Information

1.1 General

The **BD Discardit™ II** syringe is a medical single use product for injection and/or aspiration of medical fluids, including both, corporal fluids (blood, etc) and drugs. The lubricant included in the barrel material allows for a smooth advancement of the plunger without the need of a rubber ring.

REFERENCE	CAPACITY	TIP	SCALE	BOX (UNITS)	CASE (UNITS)
300928	2 ml	Concentric	0.1ml	100	3000
309050	5ml	Eccentric	0.2ml	100	1800
309110	10ml	Eccentric	0.5ml	100	1200
300296	20ml	Eccentric	1ml	80	960

1.2 Technical information

DEAD SPACE (maximum, w/o needle)

SYRINGE SIZE	2ml	5ml	10ml	20ml
Dead Space	0.07ml	0.075m	0.10ml	0.15ml

1.3 Certification

BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain	AENOR – N° ER-0097/1994 – ISO 9001:2008; AEMPS – N° 2015 05 0047EN EN – ISO 13485:2013	AEMPS N.0318 – Certificate n. 2000 06 0272CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain

1.4 Material

Component	Material
Barrel	POLYPROPYLENE
Plunger rods	POLYETHYLENE
Lubricant	AMIDE (in the barrel)
Packaging	
Web packaging	POLYAMIDE/POLYETHYLENE MEDICAL GRADE PAPER
Box	CARTON

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	Do not contain di (2ethylhexyl) phthalate DEHP as CAS number 117-81-7, EC number 204-211-0.
Latex	Do not contain natural latex
Bisphenol A	Do not contain Bisphenol A
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 (PVC)	Do not contain poly vinyl 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 or EXCEED THE FOLLOWING STANDARDS:

EN 556-1	Sterilization of Medical Devices-requirement for medical devices to be labeled "sterile"
EN 980	Graphical Symbols for use in the labeling of medical devices
EN ISO 7886-1	Sterile hypodermic syringes for single use
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 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
EN 1041	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
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 10993 series	Biological evaluation of medical devices
EN ISO 13485	Medical Devices, Quality Management Systems, Requirements for Regulatory purposes

1.11 Classification

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

1.12 GMDN code

GMDN code 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

- 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

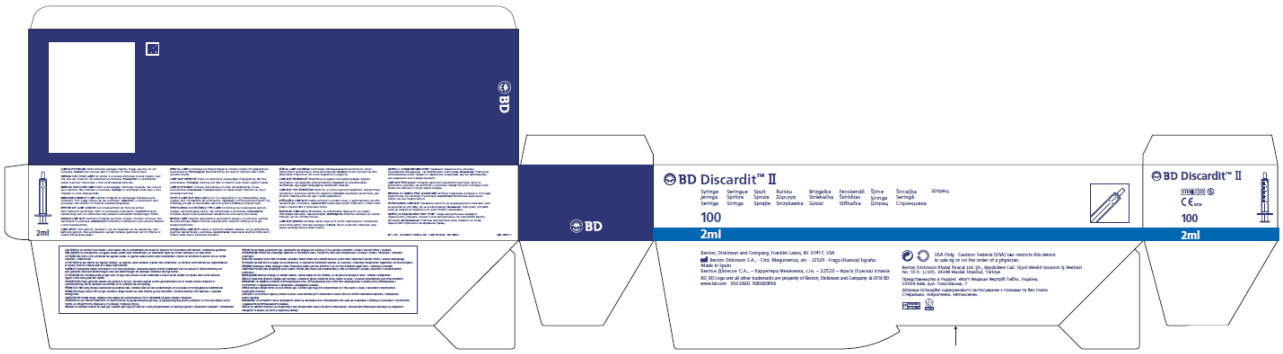
2.1 Label information

LABELS: according to European Medical Device directive, multilingual

2.2 Example labelling

Unit pack

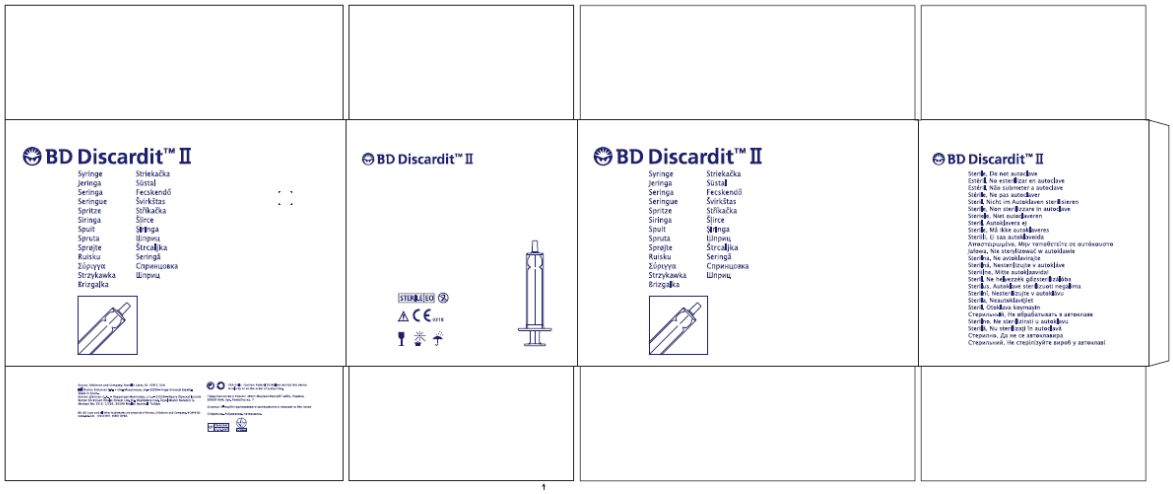
Shelf carton



Shelf-box Label

Shipping Box Label

Shipping case



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