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TECHNICAL DATA SHEET
BD Plastipak™ Syringe without needle
Sterile, Single use, Latex Free

1. General Information

1.1 General

BD Plastipak™ syringes are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin. Perfusion syringes, 50ml syringes, are designed for short term use in syringe pumps (active IIa devices) for the administration of pharmaceuticals.The 50 ml Catheter Tip Syringes have a long tapered tip designed to aid in irrigation or for connection to non-ISO compatible Luer connections such as nasogastric tubes.

LUER SLIP SYRINGES

Reference	Capacity	Description	Scale Graduation	Box (units)	Case (units)
300026	1 ml	Insulin 40 I.U.	International units	100	800
301355	1 ml	Insulin 100 I.U.	International units	100	800
303174	1 ml	Insulin 100 I.U.	International units	120	960
303173	1 ml	Insulin 40 I.U.	International units	120	960
300013	1 ml	Central cone	0.01 ml	100	800
303172	1 ml	Central cone	0.01 ml	120	960
300185	2/ 2.5 ml	Central cone	0.1 ml	100	800
302187	5 ml	Central cone	0.2 ml	100	400
302188	10 ml	Eccentric cone	0.5 ml	100	400
301183	20 ml	Eccentric cone	1 ml	60	240
300613	20 ml	Eccentric cone	1 ml	120	480
301231	30 ml	Eccentric cone	1 ml	60	240
300866	50/ 60 ml	Eccentric cone	1 ml	60	240
300867	50/ 60 ml	Catheter tip	1 ml	60	240
300605	100 ml	Catheter tip with Luer adaptor	2 ml	25	50
300869	50/ 60 ml	Luer Lock AMBER	1 ml	60	240

LUER LOK™ SYRINGES

Reference	Capacity	Description	Scale Graduation	Box (units)	Case (units)
301189	20 ml	Luer Lok™	1 ml	60	240
300629	20 ml	Luer Lok™	1 ml	120	480
301229	30 ml	Luer Lok™	1 ml	60	240
300865	50/60 ml	Luer Lok™	1 ml	60	240
300137	50 ml	Perfusion Luer Lok™	1 ml	50	100
300139	50 ml	Perfusion Amber Luer Lok™	1 ml	50	100
309628	1 ml	Luer Lok™	0.01 ml	100	800
309658	3ml	Luer Lok™	0.1ml	200	800
309649	5ml	Luer Lok™	0.2ml	125	500
300912	10ml	Luer Lok™	0.2ml	100	400

1.2 Technical information

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

SYRINGE SIZE	1 ml	2ml	5ml	10ml	20ml	30ml	50ml	100ml
Dead Space	0.07 ml	0.07ml	0.075ml	0.10ml	0.15ml	0.17ml	0.20ml	0.20ml

1.3 Certification

BD PRODUCT CODE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
(20-100 ml) 301189 301183 300629 301229 300865 300869 300867 300605 300613 301231 300866 300137 300139	Becton Dickinson & Company Limited Donore Road Drogheda Co. Louth Ireland	NSAI - Certificate MD 19.1609 I.S. EN ISO 13485:2012	NSAI NB no 0050: Certificate N°252.156	Becton Dickinson S.A. - Camino de Valdeoliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain

BD PRODUCT CODE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
(1 to 10 ml LS) 300026 301355 300013 300185 302187 302188 303172 303173 303174	Becton Dickinson S.A. - Camino de Valdeoliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain	AENOR –N. ER-0264/1994 – ISO 9001:2008; AEMPS N. 2012 07 0013 EN - EN – ISO 13485:2013	AEMPS 0318: Certificate N°2000 06 0273 CP	Becton Dickinson S.A. - Camino de Valdeoliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain
(1 ml LL) 309628	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA	NSAI - ISO 9001 :2008 Certificate MD19.2305 NSAI ISO 13485 :2012 Certificate MD19.2305	NSAI 0050: Certificate N°252.231	Becton, Dickinson and Company Route 7 & Grace Way,Canaan CT 06018 USA BD Singapore Branch, 30 Tuas Avenue 2, Singapore 639461
(3 to 10ml LL) 309658 309649 300910 300911 300912	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA	NSAI - ISO 9001 :20008 Certificate MD19.2305 NSAI ISO 13485 :2012 Certificate MD19.2305	NSAI 0050: Certificate N°252.231	Becton, Dickinson and Company Route 7 & Grace Way, Canaan CT 06018 USA

1.4 Material

COMPONENT	MATERIAL
SYRINGE	
Barrels, plunger rods	POLYPROPYLENE
Barrel cat# 309628	POLYCARBONATE
Stoppers	LATEX FREE ELASTOMER
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg/cm^2
AMBER syringes have the barrel colored to reduce U.V. light; for administration of light sensitive medications	
PACKAGING	
Web packaging	POLYAMIDE/POLYETHYLENE, PAPER WITH MEDICAL GRADE
Ink	Printing Ink
Box	HARD 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	The products 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)	The products do 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

Ethylene Oxide Sterilization following *EN ISO 11135-1*. ETO residues are within applicable regulations. All references excepting references below are sterilized with EO.

Radiation Sterilization following *EN ISO 11137-1* References sterilized with radiation: 309628, 309658,300912, and 309649.

1.9 Shelf life

Shelf life 5 years
Store in dry and warm place and not exposed to strong light.

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 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 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 11137-1*	Sterilization of health care products - Radiation. Part1.Requirements for development, validation and routine control of sterilization process for medical devices
EN ISO 11137-2	Sterilization of health care products – Radiation. Part2. Establishing the sterilization dose
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

*Some exceptions / exemptions may apply

INSULIN GRADUATED SYRINGE ALSO MEETS ISO 8537* Sterile single-use syringes, with or without needle, for insulin.

1.11 Classification

- **Class I** Sterile with a measuring function (syringes from 1 to 10 ml) Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.
- **Class IIa** (syringes from 20 to 50 ml) Medical Device under Rule 2, Annex V and VII IX 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

- The EU representative, for syringes which BD Manufacturer is Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA, is Becton Dickinson Distribution Center, Laagstraat 57, B-9140 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

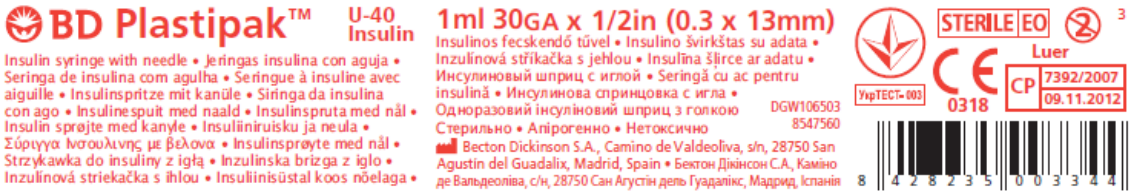
2.1 Packaging material

LABELS: according to European Medical Device directive, multilingual

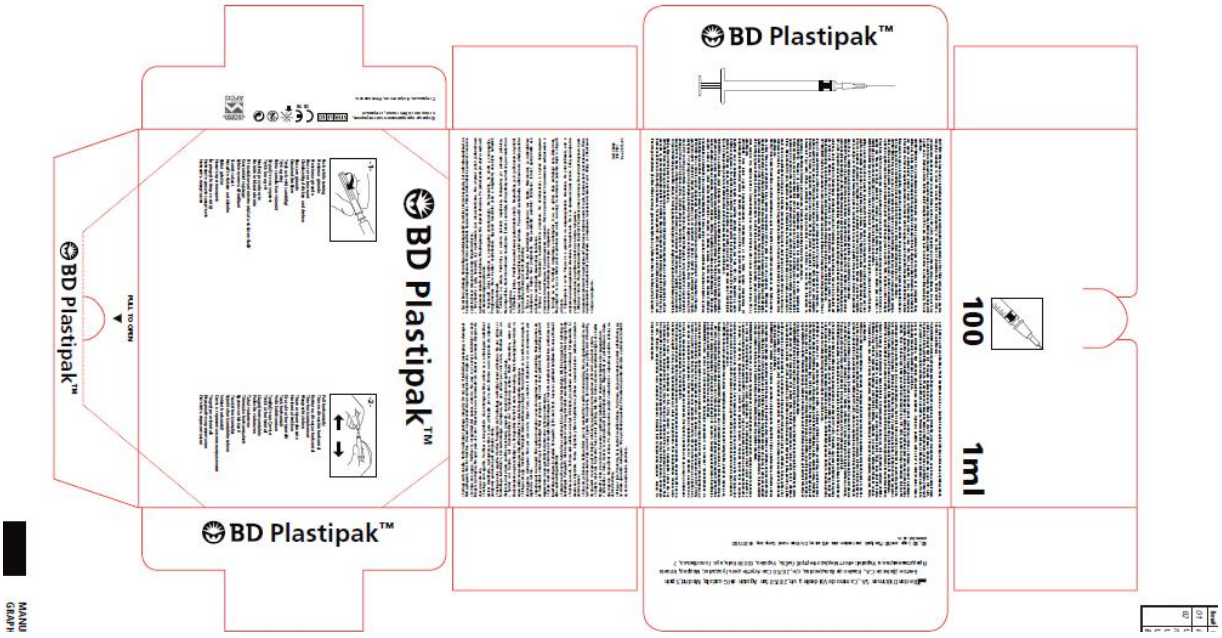
2.2 Example labeling

Manufacturer: San Agustin del Guadalix

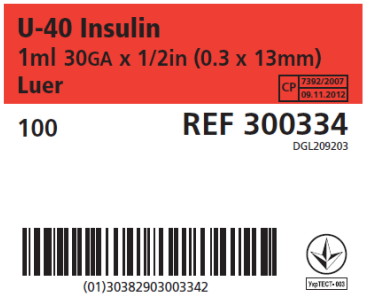
Unit pack



Shelf box

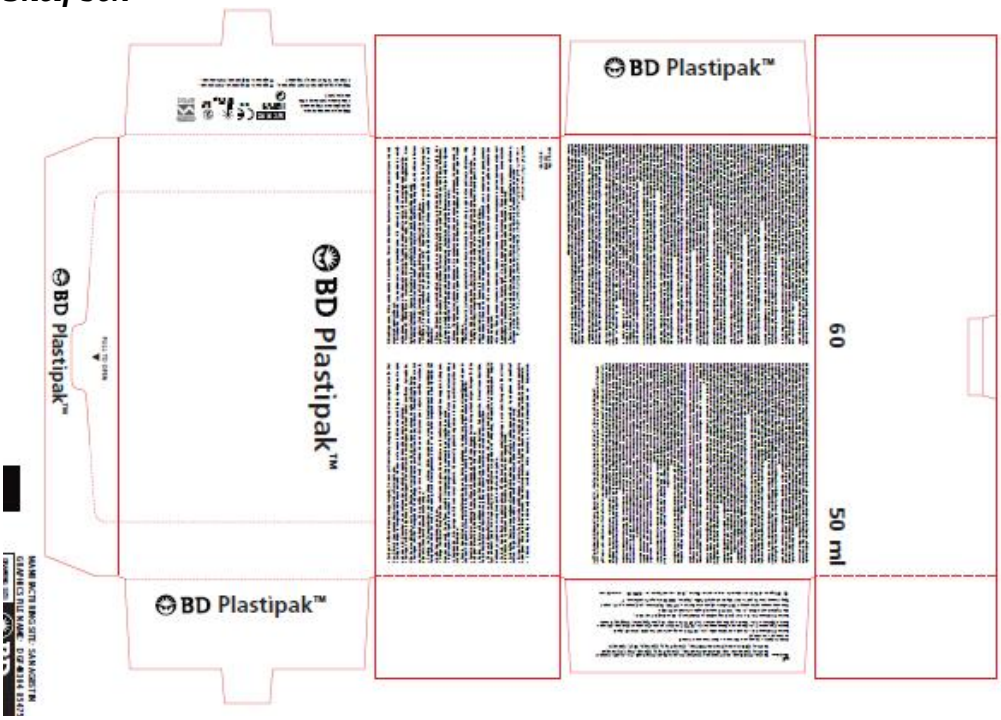


Shelf box label

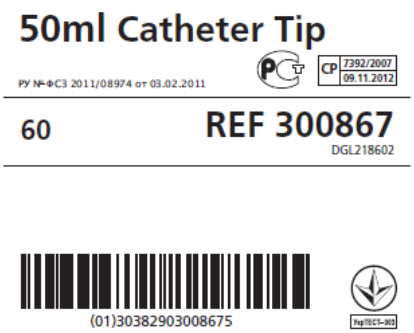


Manufacturer: Drogheda
Unit pack

Shelf box

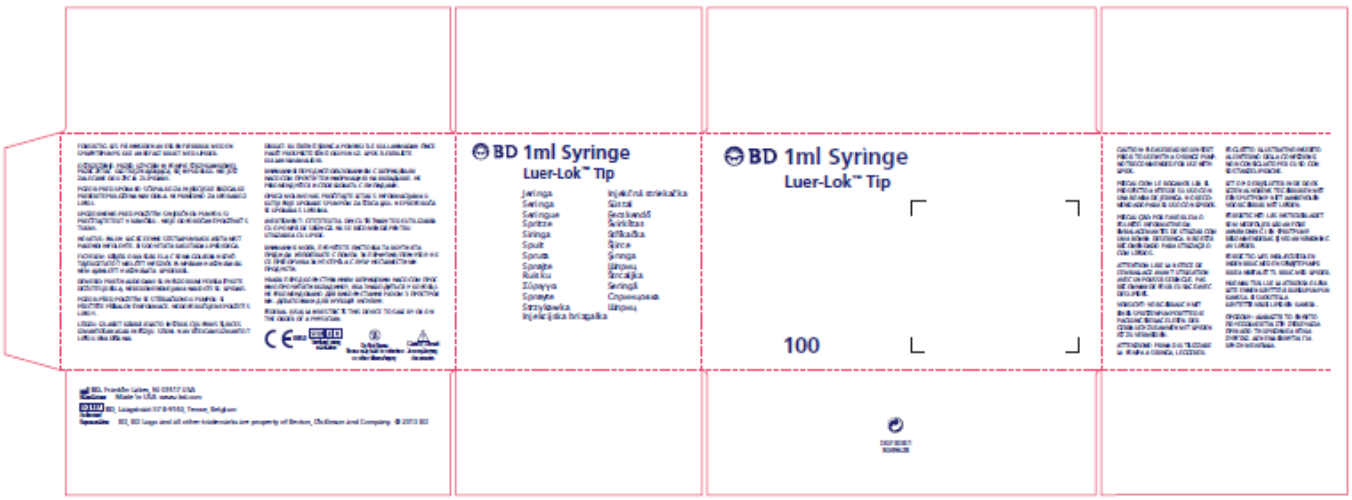


Shelf box label



Manufacturer: Franklin Lakes
Unit pack

Shelf box



Shelf box label