Becton Dickinson and Company
BD Medical,
Medication and Procedural Solution

BD Switzerland Sàrl
Terre Bonne Park - A4
Route de Crassier 17
1262 Eysins,
Switzerland

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TECHNICAL DATA SHEET

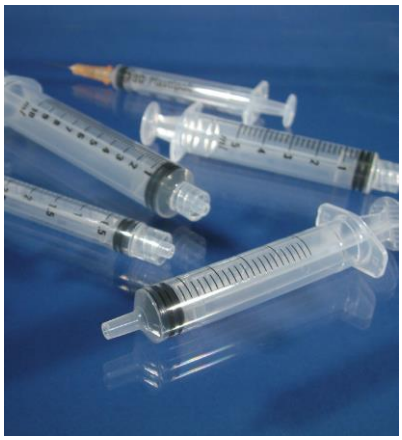
BD Plastipak™ syringes without needles and
BD General Syringes without needle
Sterile, Single Use, Latex free

1. General Information

1.1 General

BD Plastipak™ syringe and general 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.



DEAD SPACE (maximum, without 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

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Plastipak syringes without needles TDS version May 2017

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
309654	60ml	Slip tip	1 ml	40	160

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
302830	20 ml	Luer Lok™	1 ml	48	192
301229	30 ml	Luer Lok™	1 ml	60	240
300865	50/60 ml	Luer Lok™	1 ml	60	240
300137	50 ml	Luer Lok™ Perfusion	1 ml	50	100
300139	50 ml	Luer Lok™ Perfusion Amber	1 ml	50	100
309653	60 ml	Luer Lok™	1 ml	40	160
309628	1 ml	Luer Lok™	0.01 ml	100	800
309658	3 ml	Luer Lok™	0.1ml	200	800
309649	5 ml	Luer Lok™	0.2ml	125	500
300912	10 ml	Luer Lok™	0.2ml	100	400
305959*	10 ml	Luer Lok™	0.2ml	100	400
300869	50/60 ml	Luer Lok™ Amber	1 ml	60	240

**305959 will be preferred to supply to European customers as this catalogue number of 10ml Luer Lok™ Plastipak is manufactured in Europe.*

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1.2 Certification

BD REFERENCE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
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: Certifícate N° 252.156	Becton Dickinson S.A. - Camino de Valdeoliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain
300026, 301355, 300013, 300185, 302187, 302188, 303172, 303173, 303174, 305959	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: Certifícate N° 2000 06 0273 CP	Becton Dickinson S.A. - Camino de Valdeoliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain
309628*, 309658, 309649, 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: Certifícate N° 252.231	Becton, Dickinson and Company Route 7 & Grace Way, Canaan CT 06018 USA
309653, 309654, 302830	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: Certifícate N° 252.231	BD Medical - Medical Surgical Systems 2153 12th Avenue Columbus, NE 68602 USA

**Catalogue number 309628 used to be manufactured in BD Singapore Branch, 30 Tuas Avenue 2, Singapore 639461. No changes to form, fit or function when transferred to BD Canaan.*

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1.3 Material

COMPONENT	MATERIAL
Barrels	POLYPROPYLENE
Plunger rods	POLYPROPYLENE
Barrel cat# 309628	POLYCARBONATE
Stoppers	LATEX FREE ELASTOMER
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg/cm^2

BD Plastipak™ amber syringes, such as 300139 and 300869, have the barrel colored to reduce U.V. light for administration of light sensitive medications. The light transmission has been characterized as per the transparency test (method 1) as described in the Japanese Pharmacopeia XVI.

According to such method the light transmissibility (%) is characterized under a UV light source emitting at 450nm. The light transmission is 5.6± 0.2% (mean ± standard deviation) according to the transparency test.

1.4 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
Phthalates	The products do not contain phthalates. No DEHP, CAS number 117-81-1, EC number 204-211-0, intentionally added
Latex	The products do not contain natural latex.
Bisphenol A	The products do not contain Bisphenol A. Catalogue number 309628 contain polycarbonate and hence Bisphenol A
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 supppliers 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.
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

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1.5 REACH information

BD maintains an active REACH compliance program and works closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern ("SVHC") through regular communication and exchange

1.6 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.

1.7 Sterilization

- **Ethylene Oxide Sterilization** following *EN ISO 11135-1*. ETO residues are within applicable regulations. All references except references below are sterilized with EO
- **Radiation Sterilization** following EN ISO 11137-1 References sterilized with radiation: 309628, 309658, 309649, 300912, 302830, 309653 and 309654.

1.8 Shelf life

Shelf life 5 years for all catalogue numbers except 300605. Catalogue number 300605, 100ml Catheter tip, has a shelf life of 18 months. No special storage or transportation condition. Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

1.9 Standards

HARMONISED STANDARDS	
EN 556-1:2001/ AC:2006	Sterilisation of Medical Devices – requirements for medical devices to be labelled "sterile".
EN 980: 2008	Graphical Symbols for use in the labelling of medical devices.
BS EN 1041+A1: 2013	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
EN 1707:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN 20594-1:1993/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN IS010993-series	Biological evaluation of medical devices
EN ISO 11135-1:2007	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 11138-2:2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

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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 - Microbiological methods - Part 1: Determination of a population of microorganisms on products

HARMONISED STANDARDS, continue	
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
EN ISO 13485:2012/AC:2012	Medical devices – Quality management Systems Requirements for Regulatory Purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices. Application of risk management to medical devices

NON HARMONISED STANDARD	
IS EN ISO 7864-1: 1996	Sterile hypodermic needles For Single Use
IS EN ISO 7886-1:1998	Sterile hypodermic syringes For Single use - Part 1:Syringes for manual use **See Note 1 Below**
EN ISO 7886-2:1998	Sterile Hypodermic Syringes for Single Use. Part 2: Syringes for Use with Power-Driven Syringe Pumps. **See notes 2 and 3 below**
ISO 594-1:1993	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
ISO 9626: 1995	Stainless steel needle tubing for the manufacture of medical devices
ISO 13485:2003	Medical devices – Quality management Systems Requirements for Regulatory Purposes
ISO 14644-1:1999	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness
ISO 15223-1:2012	Sterilisation of Medical Devices – requirements for medical devices to be labelled “sterile”.
ISO 10993-2:2009	Biological Evaluation of Medical Devices Part 2
ISO10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 2859-1:1999	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Notes:

1. Subclause 14.1, 50ml Perfusion is non-compliant; Dead space approx. double the standard requirement (0.38ml versus 0.2ml maximum)
2. Subclause 14, Plastipak syringes (including Perfusion) do not comply as in our opinion the requirements in ISO 7886-2 section 14 are most likely not applicable to the current pump landscape and clinical requirements in the market place. Also, some of the requirements in section 14 appear questionable from a technical perspective, based on the latest state of BD’s knowledge about syringe performance on pumps and related testing capabilities

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3. Subclauses 16.1, following statement not on the labelling for Plastipak Leur Lok " Suitable for use with power-driven syringe pumps or equivalent
   INSULIN GRADUATED SYRINGE ALSO MEETS ISO 8537 Sterile single-use syringes, with or without needle, for insulin

1.10 Classification

- **Class I:** 300026, 301355, 300013, 300185, 302187, 302188, 303172, 303173, 303174 and 305959, Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.
- **Class 1**: 309628, 309658, 309649, 300912, 309653, 309654 and 302830, Rule 1, Annex IX, Section III of the Medical Device Directive 93\42\EEC as amended
- **Class IIa**: 301189, 301183, 300629, 301229 300865, 300869, 300867, 300605, 300613, 301231, 300866, 300137 and 300139, Rule 2, Annex V and VII of the Medical Devices Directive 93/42/EEC as amended.

1.11 GMDN code

GMDN code 47017: General purpose syringes.

1.12 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

1.13 Others

- The EU representative, for syringes which BD Manufacturer is BD Franklin Lakes such as 309628, 309658, 309649, 300910, 302830, 300911, 300912, 309653 and 309654 is Becton Dickinson Distribution Center, Laagstraat 57, B-9140 Temse -Belgium. Other syringes are produced by a European manufacturer.
- (Material) Safety Data 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.
- EU legislation restricting the use of hazardous substances in electrical and electronic equipment (RoHS Directive 2002/95/EC) is not applicable to these medical devices

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2. Packaging

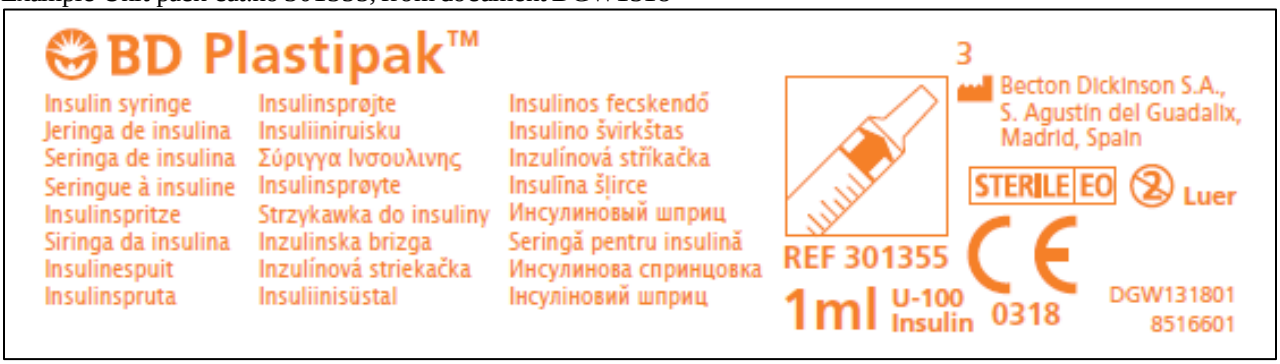
2.1 Packaging material

PACKAGING	
Web packaging	Polyamide/polyethylene, Medical grade paper
Ink	Printing Ink
Box	Hard Paper

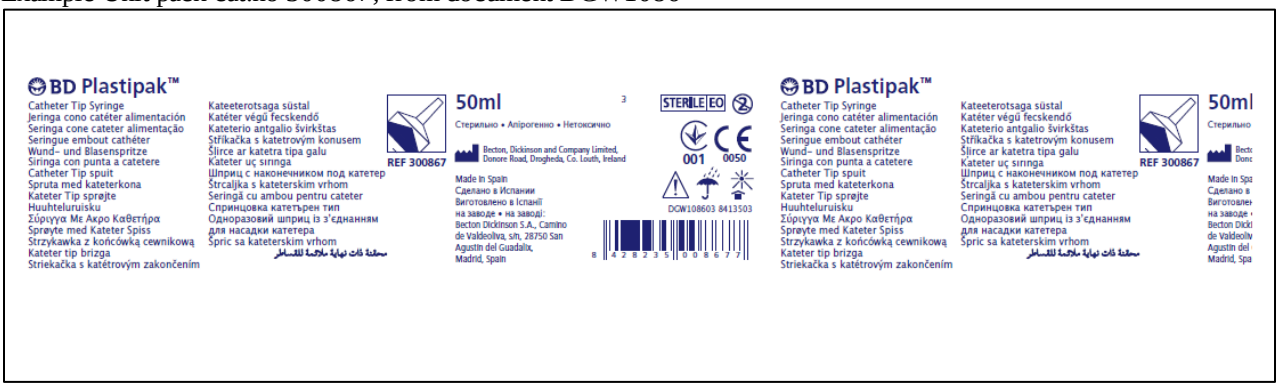
LABELS: according to European Medical Device directive, multilingual

2.2 Example labeling

Legal Manufacturer and manufacturing site: San Agustin del Guadalix
Example Unit pack cat.no 301355, from document DGW1318



Legal Manufacturer: Drogheda and manufacturing site San Agustin del Guadalix
Example Unit pack cat.no 300867, from document DGW1086



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Legal Manufacturer: Franklin Lakes and Manufacturing site Canaan
Example Unit pack cat.no 309628, from document number DGW757