Medtronic

Data sheet

BL 250 kit 015 and 025 CVVH/CVVHD

Product description

The procedure packs are captive to use on the CARPEDIEM™ machine. These procedure packs are composed by BL 250 preassembled device for hemofiltration/hemodialysis 015 for CARPEDIEM™ machine or BL 250 preassembled device for hemofiltration/hemodialysis 025 for CARPEDIEM™ machine manufactured by Bellco S.r.l and a 10 ml Luer Lok™* BD Plastipak syringe, that is manufactured by Becton Dickinson S.A.

Each preassembled device is sterile, single-use, extracorporeal circuit and consists of a dialyzer and tubing lines, that are permanently connected, and three 3-liter waste bags. The dialyzer consists of a cylindrical body that contains a bundle of hollow fibers made of high permeability polyethersulfone.

The 10 ml Luer Lok™* BD Plastipak syringe is sterile, single-use and inserted with the primary packaging in each procedure pack.

The two preassembled devices have different hollow-fiber dialyzer dimensions, HCD 015 and HCD 025, but they have the same tubing line configuration: a blood access line, a blood return line, a dialysate/infusion line, an effluent outlet line, and a heparin infusion line (figure 1).

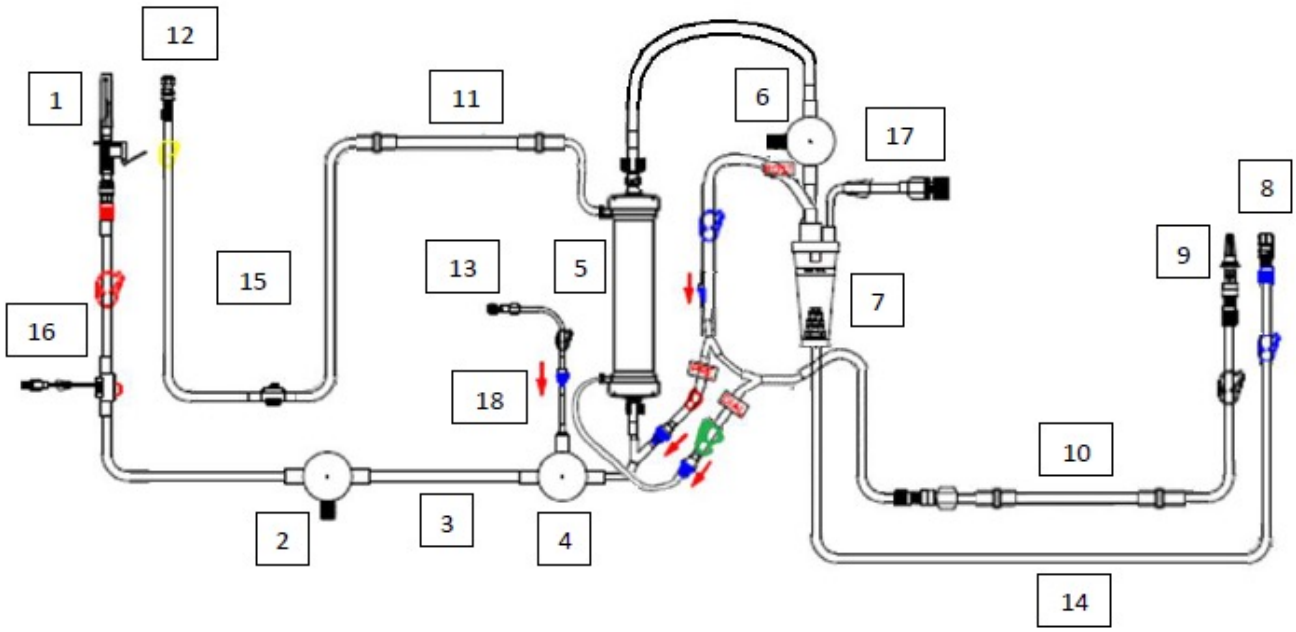

Figure 1 - legend

1. Arterial line Luer-lock
2. Arterial pressure dome
3. Blood pump segment
4. Pre-filter pressure dome
5. Filter
6. Venous pressure dome
7. Venous chamber
8. Venous line Luer-lock
9. Infusion/dialysis line Luer-lock
10. Infusion/dialysis pump segment
11. Effluent pump segment
12. Effluent line Luer-lock
13. Heparin pump line Luer-lock
14. Venous return line
15. Effluent line
16. Arterial line sampling port
17. Venous return line sampling port
18. Heparin line

Applicable therapies

The procedure packs for CARPEDIEM™ machine consist of a preassembled device and a 10 ml Luer Lok™* BD Plastipak syringe. The therapies described below depend on the use of these preassembled devices that form the procedure packs with the CARPEDIEM™ machine.

The preassembled devices are indicated for use with the CARPEDIEM™ machine in extracorporeal blood treatment for pediatric patients weighing 2.5 kilograms or more with acute kidney injury, fluid overload and/or electrolyte disorders, requiring, hemofiltration (CVVH), hemodialysis (CVVHD) or ultrafiltration/fluid removal (SCUF).

Depending on the configuration, these devices can perform the following treatments:

- Continuous Veno-Venous Hemodialysis (CVVHD) a continuous form of hemodialysis characterized by a slow dialysate flow (in-flow or counter-flow) with respect to the blood flow in the dialysate compartment of the hemodialyzer. The main solute transmembrane removal mechanism is diffusion.
- Continuous Veno-Venous Hemofiltration (CVVH) a continuous form of hemofiltration with infusion of replacement fluid upstream (pre-infusion) or downstream (post-infusion) from the hemofilter. The solute transmembrane transport mechanism is convection. The ultrafiltrate is partly or completely replaced with an appropriate replacement fluid in order to obtain effective reduction of the solute concentration and effective fluid balance.
- Slow Continuous Ultrafiltration (CVVH-SCUF) is a treatment based solely on slow removal of plasma water. It is generally used to manage patients who have fluid overload and/or are immune to pharmacologic treatment and may also have concomitant renal damage. The goal of the treatment is to achieve effective and safe correction of fluid overload. The solute concentration cannot be reduced using this treatment.

Intended use

Procedure packs for CVVH (Continuous Veno-Venous Hemofitration) and CVVHD (Continuous Veno-Venous Hemodialysis) therapies.

Codes available

Procedure pack REF	Procedure pack name	Medical device REF	Medical device name	Medical device manufacturer	CND[2]	GMDN[2]
IB0595540	BL250 KIT 015 CVVH/CVVHD	IB0580804	BL250 Preassembled device for hemofiltration/ hemodialysis 015 for CARPEDIEM™ machine	Bellco S.r.l. – Via Camurana 1 – 41037 Mirandola (MO) Italy. CE 0123	F0306	61674
		305959	BD Plastipak	Becton Dickinson S.A., Camino de Valdeoliva, s/n 28750 San Agustín del Guadalix, Madrid, Spain. CE 0318	A020102020102	47017
IB0595550	BL250 KIT 025 CVVH/CVVHD	IB0580805	BL250 Preassembled device for hemofiltration/ hemodialysis 025 for CARPEDIEM™ machine	Bellco S.r.l. – Via Camurana 1 – 41037 Mirandola (MO) Italy CE 0123	F0306	61674
		305959	BD Plastipak	Becton Dickinson S.A., Camino de Valdeoliva, s/n 28750 San Agustín del Guadalix, Madrid, Spain. CE 0318	A020102020102	47017

[2] The CND and GMDN indicated in the table refer to the preassembled and Luer Lok™* BD Plastipak syringe.

Sterilization method and validity

The Procedure Packs are non sterile and non-pyrogenic and their shelf life is of 3 years, consist of a preassembled device and a 10 ml Luer Lok™* BD Plastipak syringe.

The shelf life of the Procedure Packs is determined by the component with the shortest shelf life.

In particular, the preassembled device and the syringe are sterile and non-pyrogenic, their sterilizing agent is ethylene oxide and they cannot be re-sterilized. The shelf life of preassembled device is 3 years and instead of the syringe is 5 years.

Technical characteristics

The technical characteristics of the procedure packs components for CARPEDIEM™ machine are reported below.

Dialyzer	
Components	**Materials**
Membrane	Polyethersulfone
Housing	Copolyester
Header	Copolyester
Potting	Polyurethane
O-ring	Silicone rubber

Blood lines	
Components	**Materials**
Tubing lines	Polyvinyl chloride
Blood pump segment	Polyvinyl chloride
Infusion pump segment	Polyvinyl chloride
Heparin line	Polyvinyl chloride
Pressure transducer membrane	Silicon rubber
Tube adapter	Polyvinyl chloride
Line connector	Polyvinyl chloride (PVC) – Methyl methacrylate-acrylonitrile-butadiene-styrene (MABS)
Pressure traducer holder	Polyvinyl chloride
Venous chamber	Polyvinyl chloride
Vonous chamber filter	Polyethylene
Filter connector	Polyvinyl chloride
Access port	Polyvinyl chloride– Isoprene – Polypropylene
Clamps	Polypropylene
INF/UF luer connector ring	Polycarbonate
Vonous drip chamber service line cap	Polyvinyl chloride (PVC)
INF Y connector	Polyvinyl chloride
One-way valve	Silicon rubber – Methyl methacrylate-acrylonitrile-butadiene-styrene (MABS)
Port caps	Polypropylene
Vented spike	Acrylonitrile-butadiene-styrene (ABS) – Low density polyethylene (LDPE) – Linear Low density polyethylene (LLDPE)
Unvented spike	Acrylonitrile butadiene styrene – Low density polyethylene
INF/UF luer connector	Polyvinyl chloride

3-liter waste bag	
Components	**Materials**
Film	Polyvinyl chloride DOP free
Tube	Polyvinyl chloride DOP free
Joint female luer lock	Polyvinyl chloride
Male luer lock caps	Polypropylene
Clamp	Polypropylene

Syringe[3]	
Components	**Materials**
Barrel	Polypropylene
Piston valve	Polypropylene
Stoppers	Elastomer (LATEX free)
Lubricant	Silicone Oil (<0,25 mg/cm^2)

[3] See the technical data sheet (section n°13) provides by the manufacturer by Becton Dickinson S.A.

Technical characteristics												
Model	Dialyzer Surface area[4] (m^2)	Dialyzer fiber wall thickness (µm)	Dialyzer fiber internal diameter (µm)	Dialyzer blood compart-ment priming volume (ml)	Dialyzer maximum TMP (mmHg)	Dialyzer maximum blood flow (ml/min)	Dialyzer maximum dialysate flow (ml/min)	Dialyzer blood compartment pressure drop[5] (mmHg)		Dialyzer dialysis fluid com-partment pressure drop[6] (mmHg)	Dialyzer total length[7] (mm)	Total priming volume preas-sembled device (ml)
								Q_B 10 ml/ min	Q_B 50 ml/ min	Q_D 10 ml/min		
HCD 015	0.17	30	200	11	500	50	10	19	32	10	128	32
HCD 025	0.29	30	200	20	500	50	10	22	35	17	140	41

[4] Medium value ±10% in according with IFU
[5] Bovine blood: Hct= 32±3%, proteins = 60±5 g/l
[6] Dialysis fluid: NaCl = 0.9%
[7] Dialyzer outer body characteristic

Performance

The measurements in the charts below are taken in accordance with EN ISO 8637-1[8]. The values indicated are to be considered approximate and may vary due to measurement methods, inherent variations of the membrane, manufacturing and storage conditions. During the treatment, performance on the individual patient may vary due to variable clinical parameters of the patient.

[8] The different ISO standard mentioned in the document are in current revision.

The performances indicated below refer to the preassembled device

Dialyzer In Vitro clearance[9]																
Model	Urea (ml/min)				Creatinine (ml/min)				Phosphates (ml/min)				Vitamin B12 (ml/min)			
	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50
HCD 015	2.8	4.2	5.6	7.8	2.9	4.3	5.7	7.8	3.0	4.4	5.5	7.7	3.0	4.3	5.0	6.5
HCD 025	2.6	4.0	5.4	7.2	2.8	4.2	5.8	7.5	2.8	4.3	5.8	7.2	2.9	4.3	5.5	6.7

[9] In vitro clearance: Q_D = 10 ml/min, Q_F = 0 ml/min; saline solution: NaCl = 0.9%

Clearance at maximum Q_F and Q_D (ml/min)[10]				
Dialyzer	Urea	Creatinine	Phosphates	Vitamin B12
HCD 015[11]	10.6	10.7	10.6	9.2
HCD 025[12]	10.9	11.1	11.1	10.5

[10] Saline solution: NaCl = 0.9%, Q_D = 10 ml/min
[11] Q_F = 14 ml/min, Q_B = 50 ml/min, Q_D = 10 ml/min
[12] Q_F = 15 ml/min, Q_B = 50 ml/min, Q_D = 10 ml/min

Ultrafiltration coefficient		
Dialyzer	K_{uf}[13] (ml/h*mmHg)	
	Q_B 10 ml/min	Q_B 50 ml/min
HCD 015	4.8	9.8
HCD 025	9.0	22.1

[13] Bovine blood Hct = 25±2%, proteins = 60 g/l

Sieving coefficient		
Marker	HCD 015	HCD 025
Inulin	0.8	0.8
Myoglobin	0.34	0.34
Albumin	0.002	0.002

Packaging

Model	Primary packaging		
	Pouch material	Tray	Pouch weight (g)
BL250 015 KIT 015 CVVH/CVVHD	Polyester/ Polypropylene Medical grade paper 60g/m²	Polypropylene	30.0
BL250 025 KIT 025 CVVH/CVVHD	Polyester/ Polypropylene Medical grade paper 60g/m²	Polypropylene	30.0
10 ml Luer Lok™* BD Plastipak Syringe	Polyamied/Polyethylene Medical grade paper	N.A.	1.3

Model	Secondary packaging – Box				
	Single box	Weight[14] (kg)	Multiple box	Weight[15] (kg)	Pcs/ Box[16]
BL250 KIT 015 CVVH/CVVHD	White colored Rippled Cardboard 4 mm – KBM/222/B Dimensions: 560 × 377 × 71 mm	0.9	Avana colored Rippled Cardboard 4 mm Dimensions: 590 × 390 × 324 mm	4.4	4
BL250 KIT 025 CVVH/CVVHD	White colored Rippled Cardboard 4 mm – KBM/222/B Dimensions: 560 × 377 × 71 mm	0.9	Avana colored Rippled Cardboard 4 mm Dimensions: 590 × 390 × 324 mm	4.5	4

[14] Single box weight

[15] Multiple box weight

[16] Number of single boxes insert into the multiple box

Storage and disposal conditions

Storage conditions: store at temperatures between +5 and +30 degrees Celsius.

Disposal: dispose the device after treatment in accordance with applicable government and health center regulations.

Biocompatibility

Biocompatibility tests of the preassembled devices and syringe for CARPEDIEM™ machine have been performed according to EN ISO 10993-1[17] and related applicable standard series.

Biocompatibility tests are the responsibility of the manufacturer of the medical devices inside the procedure packs.

[17] The different ISO standard mentioned in the document are in current revision.

Technical data sheet syringe BD plastipak

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TECHNICAL DATA SHEET

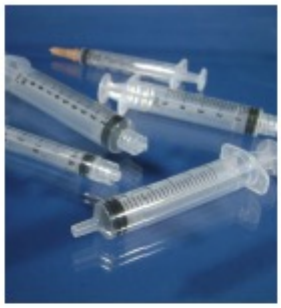
BD Plastipak™ syringes without needles and BD General Syringes without needle Sterile, Single Use, Latex free

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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Technical data sheet syringe BD plastipak (continued)

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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.*

Technical data sheet syringe BD plastipak (continued)

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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: Certificate N° 252.156	Becton Dickinson S.A. - Camino de Valdeolliva, 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 Valdeolliva, 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 Valdeolliva, s/n. 28750, San Agustin del Guadalix (Madrid) Spain
309628*, 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
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: Certificate 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.*

Technical data sheet syringe BD plastipak (continued)

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1.3 Material

COMPONENT	MATERIAL
SYRINGE	
Barrels, plunger rods	POLYPROPYLENE
Barrel cat# 309628	POLYCARBONATE
Stoppers	LATEX FREE ELASTOMER
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg/cm²

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 products were assessed for TSE (Transmissible Spongiform Encephalopathy) contamination risk. The raw materials used in the manufacture of this device do not contain any animal tissue but may contain very small amounts of animal derived raw materials. This product is manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow derived materials have been produced using multiple cycles of conditions at least as rigorous (and normally more rigorous) as those specified in Annex C.5 of EN ISO 22442-1. Therefore, the raw materials meet or exceed the requirements of EN ISO 22442-1. Therefore, the raw materials meet or do not to present any risk with respect to TSE or other animal borne disease
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

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

Technical data sheet syringe BD plastipak (continued)

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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, 300910, 300911, 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 ISO10993-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
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

Technical data sheet syringe BD plastipak (continued)

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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
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

Technical data sheet syringe BD plastipak (continued)

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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, 300910, 300911, 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.

Technical data sheet syringe BD plastipak (continued)

Becton Dickinson and Company
BD Medical,
Medication and Procedural Solution

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

bd.com

2. Packaging

2.1 Packaging material

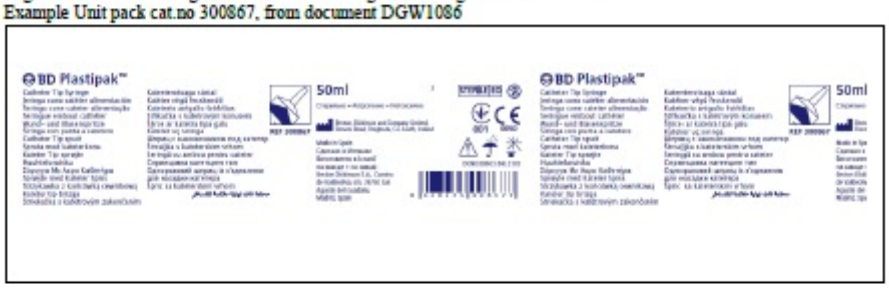
PACKAGING	
Web packaging	Polyamied/polyethylene, Medical grade paper
Ink	Printing Ink
Box	Hard Paper

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



ment is approved electronically
ment can be changed without further notification

Technical data sheet syringe BD plastipak (continued)

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

Notes

Medtronic

Bellco S.r.l.
Via Camurana, 1
41037 Mirandola (MO) Italy
Tel: +39 0535 29111

www.bellco.net

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.