Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

TECHNICAL DATA SHEET

BD Safetyglide™ Syringe & Needle
Sterile, Latex free

1. General Information

1.1 General

Single use latex free sterile syringe, for injection and infusion, with permanently attached needle and safety shield.



BD SafetyGlide™ TNT syringe with integrated needles:

BD catalogue number	Capacity	Description	Scale Graduation	Box (units)	Case (units)
305945	1 ml	27G ½" (13 mm)	0.01ml	100	400
305946	1 ml	26G 3/8"(10mm)	0.01ml	100	400

The syringe BD SafetyGlide™ TNT (Tiny Needle technology) ensures the safety of intra-dermal or subcutaneous injections. The contaminated needle can be covered, one-handedly, immediately after the injection and the withdrawal of the needle, by simply pushing, with one finger (thumb or index), the protective cap over the needle tip until a « click » is heard. The safety device can be rotated to allow a perfect readability of the graduation during the preparation of the injection and to allow for low-angle injections.

BD SafetyGlide™ Combo needle with BD Luer lok™ syringe:

BD catalogue number	Capacity	Description	Scale Graduation	Box (units)	Case (units)
305904	3ml	25G 5/8"(12mm)	0.1ml	50	400
305905	3 ml	23G 1"(8mm)	0.1ml	50	400
305907	5 ml	22G 1 1/2"(25mm)	0.2ml	50	400
305908	10 ml	22G 1 1/2"(25mm)	0.5ml	50	400

Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

1.2 Certification

BD CATALOGUE NUMBER	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
305945, 305946	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA	NSAI - ISO 9001 :2008 Certificate MD19.2305 – ISO 13485 :2012 Certificate MD19.2305	NSAI 0050: Certificate N°252.231	Becton, Dickinson and Company 1329 West Highway 6, Holdrege, NE 68949 USA
305904, 305905				Becton Dickinson Canaan Route 7 & Grace Way Canaan CT 06018 USA
305907, 305908				BD Medical Systems Periferico Luis Donaldo Colosio #578 Nogales, Sonora CP 84048, Mexico

1.3 Material

Component		Raw Material
Needle	Cannula	Stainless Steel
	Hub	Polypropylene
	Clip for Luer Slip application	Stainless Steel/Polypropylene
	Shield	Polypropylene
	Lubricant	Medical Grade Silicone
	Adhesive	UV cured. Eclipse is heat cure
SafetyComponents	Safety Arm	Polypropylene
	SafetyLatch	Stainless Steel
	Adhesive	Epoxy (UV cured)

Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

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
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	Bisphenol A might be found in very low amount (at a concentration inferior to 5ppm) as a residue from the epoxy synthesis processing.
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

1.5 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).

1.6 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

Sterilization method: **Radiation Sterilization** following *EN ISO 11137-1*

1.8 Shelf life

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

Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

1.9 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 ISO 10993 series	Biological evaluation of 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 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
ISO 7864	Sterile hypodermic needles for single use
EN 20594-1/ISO 594-1	Conical fitting with 6% (Luer) taper for syringes, needles ….
EN 1707/ISO 594-2:	Conical Fittings with a 6 % (Luer) Taper for Syringes, needles.."— Lock Fittings
ISO 6009:	Hypodermic needles for single use – Color coding for identification"
	*305945 and 305946 do not meet the EN 20594-1/ISO594-1 or the EN1707/ISO594-2 standards

SCALE MARKINGS– ISO Standard

1.10 Classification

Class IIa Medical Devices as per Annex IX, Section III, Rule 6 of the Medical Device Directive 93/42/EEC as amended.

1.11 GMDN code

GMDN code 47017

Advancing the world of health

Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

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 is Becton Dickinson Distribution Center, Laagstraat 57, B-9140 Temse -Belgium.
- 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

Component	Raw Material
Top Web	Medical Grade Paper/Plastic film
Bottom Web	Thermoformable Plastic
Shelf Carton	Corrugated Carton
Ship Case	Corrugated Carton/PE shrink film
Allergist Tray	Polystyrene

PRINT: PERMANENT TYPE BLACK INK
LABELS: according to European Medical Device directive, multilingual

Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

2.2 Example labeling

Example Unit pack, catalogue number 305908



_____end of document_____

Advancing the world of health