

**BD™ Oral Syringes,
Non-Sterile,**

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

**305207 – 305208 – 305209 – 305210 – 305217 –
305218 – 305219 – 305220**

TDS number: V201-044 – Rev. 01
2019-July

1. General Information

1.1 Intended use

The BD Oral syringes are used for the transport and administration of non-injectable liquid medication.

1.2 General description

The BD Oral Syringe assembly consists of a polypropylene barrel imprinted with a graduated scale in milliliters and barrels are available in either clear or amber. The BD Oral Syringe connector is a non-luer design that cannot be mated to a luer (6% taper) connector due to its larger outer diameter and non-tapered design.



BD Catalog Number	BD Product Description	Capacity	Color
305207	SYRINGE ORAL 1ML AMBER	1ml	Amber
305208	SYRINGE ORAL 5ML AMBER	5ml	Amber
305209	SYRINGE ORAL 10ML AMBER	10ml	Amber
305210	SYRINGE ORAL 3ML AMBER	3ml	Amber
305217	SYRINGE ORAL 1ML CLEAR	1ml	Clear
305218	SYRINGE ORAL 5ML CLEAR	5ml	Clear
305219	SYRINGE ORAL 10ML CLEAR	10ml	Clear
305220	SYRINGE ORAL 3ML CLEAR	3ml	Clear

Please check BD catalog number availability in your country.

Further features: N/A

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1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
305207 305208 305209 305210 305217 305218 305219 305220	Address: Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States ISO 13485 Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.308	Address: Becton, Dickinson and Company Route 7 and Grace Way Canaan, CT 06018 USA ISO 13485 Certificate No.: MD19.2369	Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium

1.4 Materials

Component	Material
Barrel	Polypropylene
Plunger rod	Polypropylene
Stopper	Synthetic Rubber
Lubricant	Medical Grade Silicone
Tip Cap	Polyethylene
Colorant	Translucent Amber Color Concentrate (For reference 305207, 305208, 305209 and 305210 only)

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1.5 Materials 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	<p>Based on our ongoing data collection efforts and/or information received from our suppliers as per 29 April 2019, BD has not identified any</p> <ul style="list-style-type: none"> • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-S), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis(2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • N-pentyl-isopentylphthalate (CAS# 776297-69-9) or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) <p>in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).</p>
Latex	<p>Based on our ongoing data collection efforts and/or information received from our suppliers as per 29 April 2019, the articles with the Product Numbers above are not formulated with natural rubber latex.</p>
Bisphenol A	<p>Based on our ongoing data collection efforts and/or information received from our suppliers as per 29 April 2019, BD has not identified any</p> <ul style="list-style-type: none"> • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) <p>in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).</p>
Substances of animal origin BSE/TSE	<p>The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acids and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN 22442-1:2015 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/ 01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, as recognized by MEDDEV 2.4/1, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC and EU No 722/2012).</p>
Polyvinyl chloride (PVC)	<p>The medical devices and packaging referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.</p>

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 29 April 2019, BD has 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 27 June 2018 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

The Oral Syringes are non-sterile devices.

1.9 Shelf life and storage conditions

The BD™ Oral Syringes are non-sterile devices and therefore, shelf life is not claimed on these devices.

1.10 Standards

As per extract from the Declaration of Conformity number DOC DTF0005 linked to CE certificate number 252.308:

Harmonized Standards	
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 13485:2016	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.
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN 22442-1:2007	Medical devices utilizing animal tissues and their derivatives -- Part 1: Application of risk management
EN 22442-2:2007	Medical devices utilizing animal tissues and their derivatives -- Part 2: Controls on sourcing, collection and handling

Note:

The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

Oral Syringes is a Class I, Non-Sterile measuring Medical Device according to Rule I of Annex IX.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Oral Syringes are referenced as follows:

GMDN Code: 45153

GMDN Term: Oral Medicine Administration Kit

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.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food*) 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.
- BD™ Oral Syringes are compliant to USP light transmission limits.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Shelf Box** (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
305207	SYRINGE ORAL 1ML AMBER	100	500	Yes
305208	SYRINGE ORAL 5ML AMBER	100	500	Yes
305209	SYRINGE ORAL 10ML AMBER	100	500	Yes
305210	SYRINGE ORAL 3ML AMBER	100	500	Yes
305217	SYRINGE ORAL 1ML CLEAR	100	500	Yes
305218	SYRINGE ORAL 5ML CLEAR	100	500	Yes
305219	SYRINGE ORAL 10ML CLEAR	100	500	Yes
305220	SYRINGE ORAL 3ML CLEAR	100	500	Yes

*"No": IFU may be available but not as an insert.

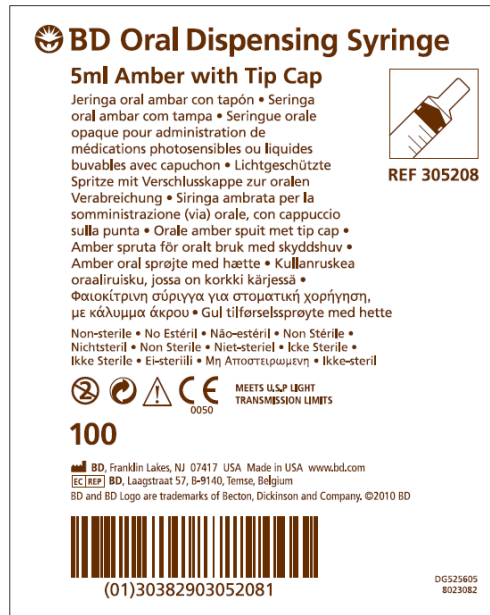
**replaced by a bag

2.2 Packaging material

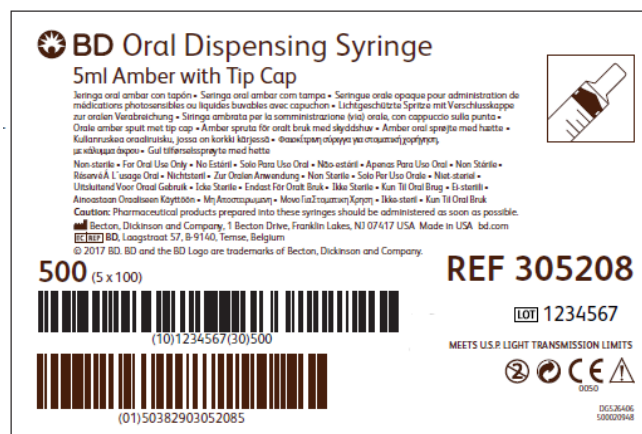
Component	Material
Bag	Polyethylene
Shipping Case	Corrugated Carton
IFU	Paper

2.3 Examples of labeling

Bag Label extracted from document DG5256 related to reference 305208:



Case label extracted from document DG5264 related to reference 305208:






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IFU (English part) extracted from document DG1873 related to reference 305208:

English

BD Oral Dispensing Syringe with Tip Cap

Instructions For Use

1. Accurately measure prescribed dosage using the top edge of the stopper. Syringe scales are indicated in milliliters (mL). 
2. After filling syringe, attach tip cap which is provided separately in small bag. 
3. Before dispensing, **REMOVE TIP CAP** and position syringe tip in the pocket between the cheek and the back teeth (molars). 
4. To avoid choking, slowly dispense the medication by pushing gently on the plunger rod.
5. Discard syringe properly after use.

NOTE: Non-Sterile • Single Use • For Oral Use Only




Caution: Reuse may lead to infection or other illness/injury.

This product is not made with natural rubber latex.

Oral Dispensing Syringe will not accept a hypodermic needle.

Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417 USA
Manufacturer

BD, Laagstraat 57, B-9140, Temse, Belgium
Made in USA

Do Not Reuse   

REVISION	CHANGE SUMMARY
01	Initial release according to new template

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