

BD Medical

The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford, Oxfordshire, OX4 4DQ
tel: +44 (0)1865 748844
fax: +44(0)1865 717313
www.bd.com



TECHNICAL DATA SHEET

BD Oral Syringes

Multiple use, Non Sterile, Latex Free

1.1 General

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



Code	Capacity	Description	Colour	Case Units
305217	1 ml	Oral syringe	Clear	500
305220	3 ml	Oral syringe	Clear	500
305218	5 ml	Oral syringe	Clear	500
305219	10 ml	Oral syringe	Clear	500
305207	1 ml	Oral syringe	Amber	500
305210	3 ml	Oral syringe	Amber	500
305208	5 ml	Oral syringe	Amber	500
305209	10 ml	Oral syringe	Amber	500

Case of 5 plastic bags each contains 100 units.



1.2 Certification

BD PRODUCT	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
Oral Syringe	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°252.308	Becton Dickinson Canaan Route 7 & Grace Way Canaan CT 06018 USA

1.3 Material

COMPONENT	MATERIAL
Barrels, plunger rods	POLYPROPYLENE
Stoppers	SYNTHETIC RUBBER
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg/cm ²
Colorant (Amber syringes only)	TRANSLUCENT AMBER COLOUR CONCENTRATE
Tip cap	POLYETHYLENE
PACKAGING	
Tip Cap bag	ETHYLENE VINLY ACETATE BAG
Bag	POLYETHYLENE BAG
Ship case	CORRUGATED CARTON

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	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-

1.5 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

This product is sold non sterile.

1.8 Shelf life

Shelf life 5 years

Store in dry and warm place and not exposed to strong light.

1.9 Standards

STANDARD	TITLE
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	Biological Evaluation of Medical Devices Part-1: Evaluation and Testing
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 22442-1	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
EN ISO 22442-2	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
EN ISO 7886-1*	Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use - First Edition; Replaces ISO 7886; Corrigendum 1-1995

*with the exception of sterility and Sections 10.1, 13.1, 16.2h, 16.3f.

1.10 Classification

Oral Syringes are Class I Medical Devices, non-sterile with a measuring function, as per Annex IX, Section III, Rule 1 of the Medical Device Directive 93/42/EEC.

1.11 GMDN code

GMDN code 45153 Oral medicine administration kit

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) Safety Data Sheets are not required for this product

1.14 Labelling

Example of labelling Case Label, catalogue number 305207

This document is approved electronically

This document can be changed without further notification



BD Oral Dispensing Syringe
1ml Amber with Tip Cap

Jeringa oral ambar con tapón • Seringa oral ambar com tampa • Seringue orale opaque pour administration de médicaments photosensibles ou liquides buvables avec capuchon • Lichtgeschützte Spritze mit Verschlusskappe zur oralen Verabreichung • Siringa ambra per la somministrazione (via) orale, con cappuccio sulla punta • Orale amber spuit met tip cap • Amber spruta för oralt bruk med skyddshuv • Amber oral sprejte med hette • Käyttäminen oraaliin, jossa on korkki kärjessä • Φαλοκίτρινη σύριγγα για στοματική χορήγηση, με κάλυμμα άκρου • Gul tilførselsprøyte med hette

Non-sterile • For Oral Use Only • No Estéril • Solo Para Uso Oral • Não-estéril • Apenas Para Uso Oral • Non Stérile • Réservé À Usage Oral • Nichtsteril • Zur Oral Anwendung • Non Sterile • Solo Per Uso Orale • Niesteril • Alleen Voor Oral Gebruik • Ikke Steril • Endast För Oralt Bruk • Ikke Steril • Kun Til Oral Brug • Ei-steril • Μη Αποστειρωμένη • Ikke-steril • Kun Til Oral Bruk

BD, Franklin Lakes, NJ 07417 USA. Made in USA. www.bd.com
 BD, Laagstraat 57, B-9140, Temse, Belgium
 BD and BD Logo are trademarks of Becton, Dickinson and Company. ©2010 BD

500 (5 x 100) **REF 305207**

MEETS U.S. LIGHT TRANSMISSION LIMITS

(01)50382903052078

0050

06225265
8423729

Example of Poly Bag Label, catalogue number 305207

BD Oral Dispensing Syringe
1ml Amber with Tip Cap

Jeringa oral ambar con tapón • Seringa oral ambar com tampa • Seringue orale opaque pour administration de médicaments photosensibles ou liquides buvables avec capuchon • Lichtgeschützte Spritze mit Verschlusskappe zur oralen Verabreichung • Siringa ambra per la somministrazione (via) orale, con cappuccio sulla punta • Orale amber spuit met tip cap • Amber spruta för oralt bruk med skyddshuv • Amber oral sprejte med hette • Käyttäminen oraaliin, jossa on korkki kärjessä • Φαλοκίτρινη σύριγγα για στοματική χορήγηση, με κάλυμμα άκρου • Gul tilførselsprøyte med hette

Non-sterile • No Estéril • Não-estéril • Non Stérile • Nichtsteril • Non Sterile • Nie-steril • Ikke Sterile • Ikke Sterile • Ei-steril • Μη Αποστειρωμένη • Ikke-steril

BD, Franklin Lakes, NJ 07417 USA. Made in USA. www.bd.com
 BD, Laagstraat 57, B-9140, Temse, Belgium
 BD and BD Logo are trademarks of Becton, Dickinson and Company. ©2010 BD

100 **REF 305207**

MEETS U.S. LIGHT TRANSMISSION LIMITS

(01)30382903052074

00225485
0623088

-----end of document-----