**Becton Dickinson and Company**
**BD Medical**

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

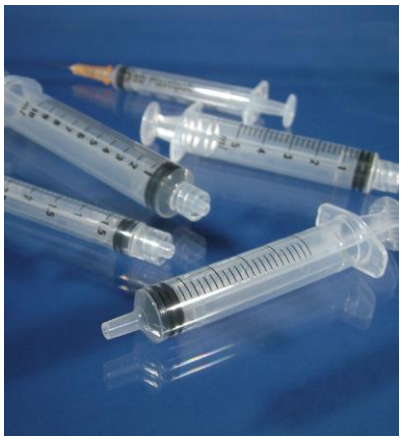
# TECHNICAL DATA SHEET

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

## 1. General Information

### *1.1 General*

BD Plastipak™ 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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## 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 |
| 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 | 60ml | Luer Lok™ | 1 ml | 40 | 160 |
| 309628 | 1 ml | Luer Lok™ | 0.01 ml | 100 | 800 |
| 309658 | 3ml | Luer Lok™ | 0.1ml | 200 | 800 |
| 309649 | 5ml | Luer Lok™ | 0.2ml | 125 | 500 |
| 300912 | 10ml | Luer Lok™ | 0.2ml | 100 | 400 |
| 305959* | 10ml | 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.*



## *1.2 Certification*

| BD REFERENCE | BD MANUFACTURER | ISO CERTIFICATION | CE MARKING | BD MANUFACTURING SITE |
|---|---|---|---|---|
| 301189<br>301183<br>300629<br>301229<br>300865<br>300869<br>300867<br>300605<br>300613<br>301231<br>300866<br>300137<br>300139 | Becton Dickinson & Company Limited<br>Donore Road<br>Drogheda<br>Co. Louth<br>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<br>301355<br>300013<br>300185<br>302187<br>302188<br>303172<br>303173<br>303174<br>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;<br><br>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*<br>309658<br>309649<br>300910<br>300911<br>300912<br>309653<br>309654 | Becton, Dickinson and Company<br>1 Becton Drive<br>Franklin Lakes, NJ 07417, USA | NSAI - ISO 9001 :20008 Certificate MD19.2305<br><br>NSAI ISO 13485 :2012 Certificate MD19.2305 | NSAI 0050: Certifícate N° 252.231 | Becton, Dickinson and Company<br>Route 7 & Grace Way,<br>Canaan CT 06018<br>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 |
|---|---|
| SYRINGE | |
| Barrels, plunger rods | POLYPROPYLENE |
| Barrel cat# 309628 | POLYCARBONATE |
| Stoppers | LATEX FREE ELASTOMER |
| Lubricant | MEDICAL GRADE SILICONE OIL, <0.25 mg/cm$^2$ |
| AMBER syringes have the barrel colored to reduce U.V. light; for administration of light sensitive medications | |
| | |
| PACKAGING | |
| Web packaging | POLYAMIDE/POLYETHYLENE, PAPER WITH MEDICAL GRADE |
| Ink | Printing Ink |
| Box | HARD PAPER |

## *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 in general and as such 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.<br>Catalogue number 309628 contain polycarbonate and hence Bisphenol A |
| Substances of animal origin BSE/TSE | The products do use industrial raw materials which contain small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Such substances are not considered as derivatives of animal tissues for the purpose of this rule (EU regulation 722/2012) 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. 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.

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## *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, 309653 and 309654.

## *1.8 Shelf life*

Shelf life 5 years
No special storage or transportation condition. Recommendations to store in room temperature. Store 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 |
| 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 |
| 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) |

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| **HARMONISED STANDARDS, continue** | |
|---|---|
| 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 |
| 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 |

INSULIN GRADUATED SYRINGE ALSO MEETS ISO 8537 Sterile single-use syringes, with or without needle, for insulin

## *1.10 Classification*

- **Class I** Sterile with a measuring function (syringes from 1 to 10 ml) Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.
- **Class IIa** (syringes from 20 to 50 ml) Medical Device under Rule 2, Annex V and VII IX of Medical Devices Directive 93/42/EEC as amended.

## *1.11 GMDN code*

GMDN code 47017: General purpose syringes.

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## ***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 Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA, 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.

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## 2. Packaging

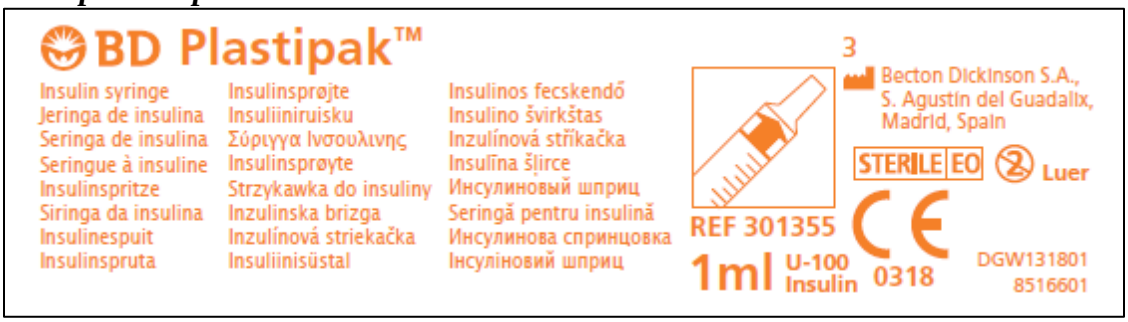
### *2.1 Packaging material*

LABELS: according to European Medical Device directive, multilingual

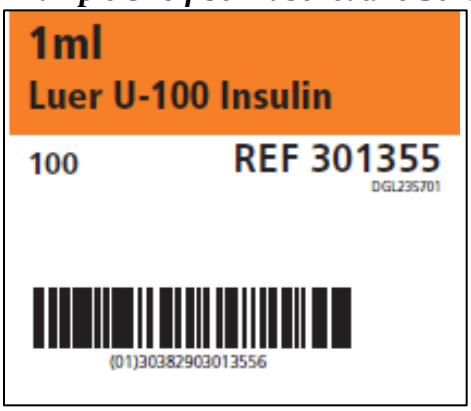
### *2.2 Example labeling*

***Legal Manufacturer and manufacturing site: San Agustin del Guadalix***

***Example Unit pack cat.no 301355***




***Example Shelf box label cat.no 301355***



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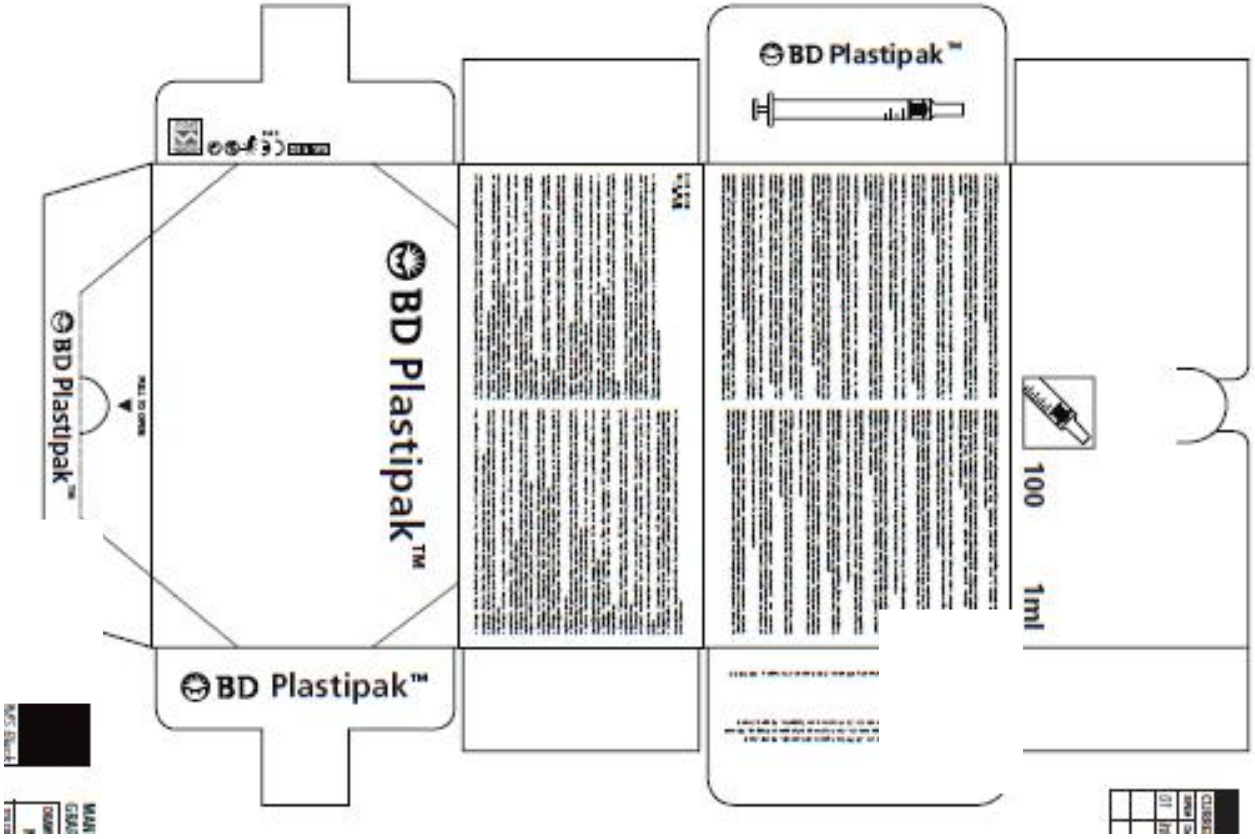
## *Shelf box graphics*



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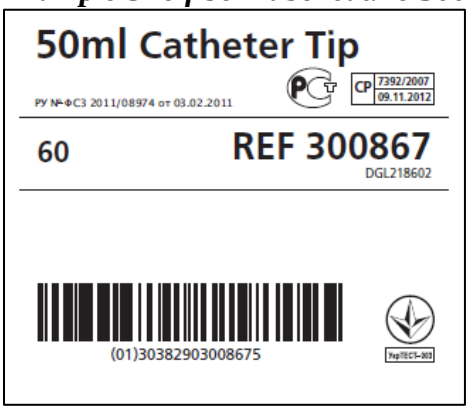
## *Legal Manufacturer: Drogheda/ Manufacturing site San Agustin del Guadalix*

## *Example Unit pack cat.no 300867*


## *Example Shelf box label cat.no 300867*



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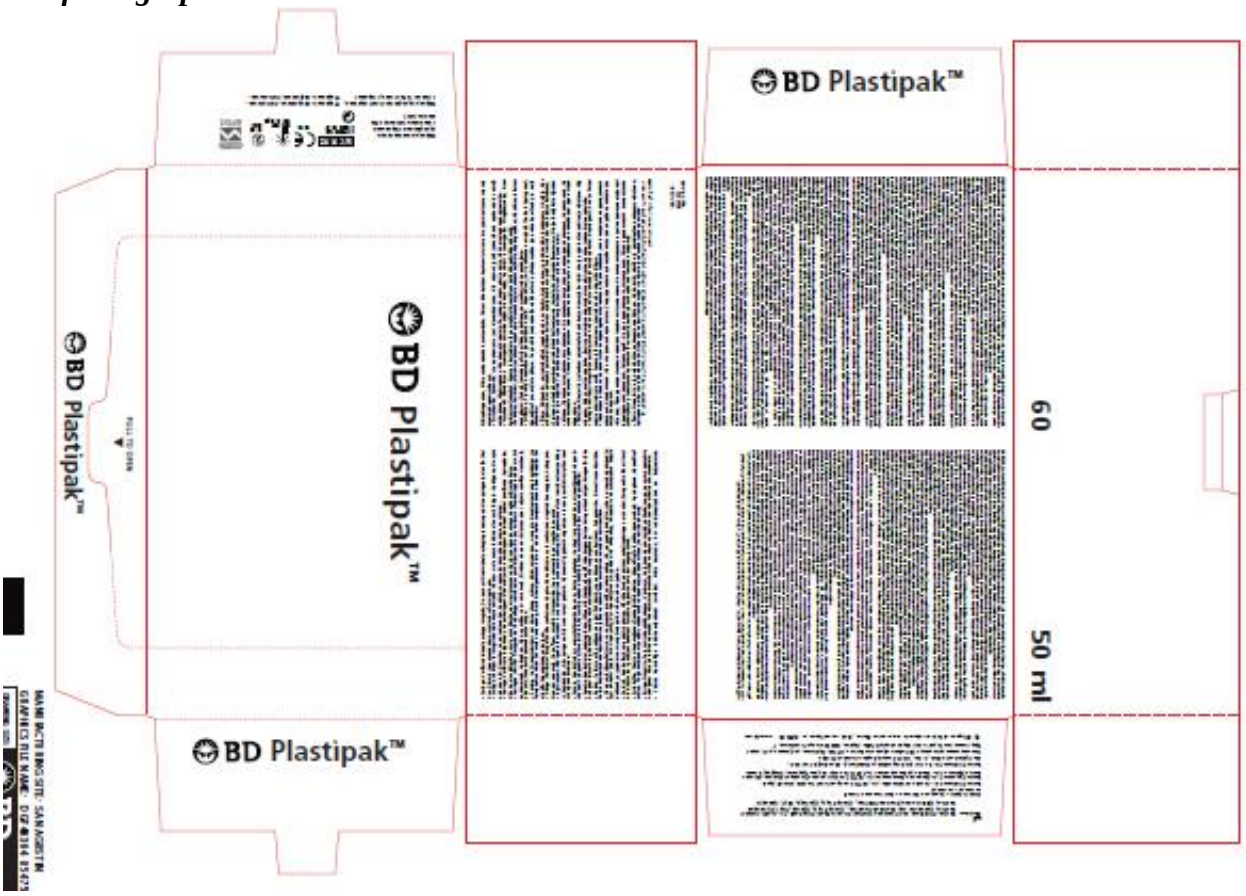
## *Shelf box graphics*



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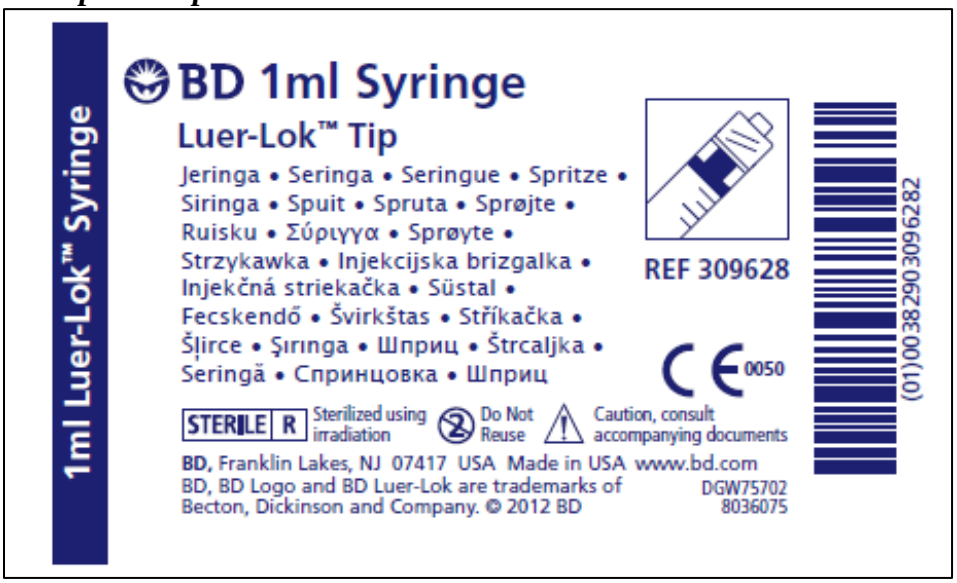
***Legal Manufacturer: Franklin Lakes, Manufacturing site Canaan***

***Example Unit pack cat.no 309628***




***Exmaple Shelf box label cat.no 309628***

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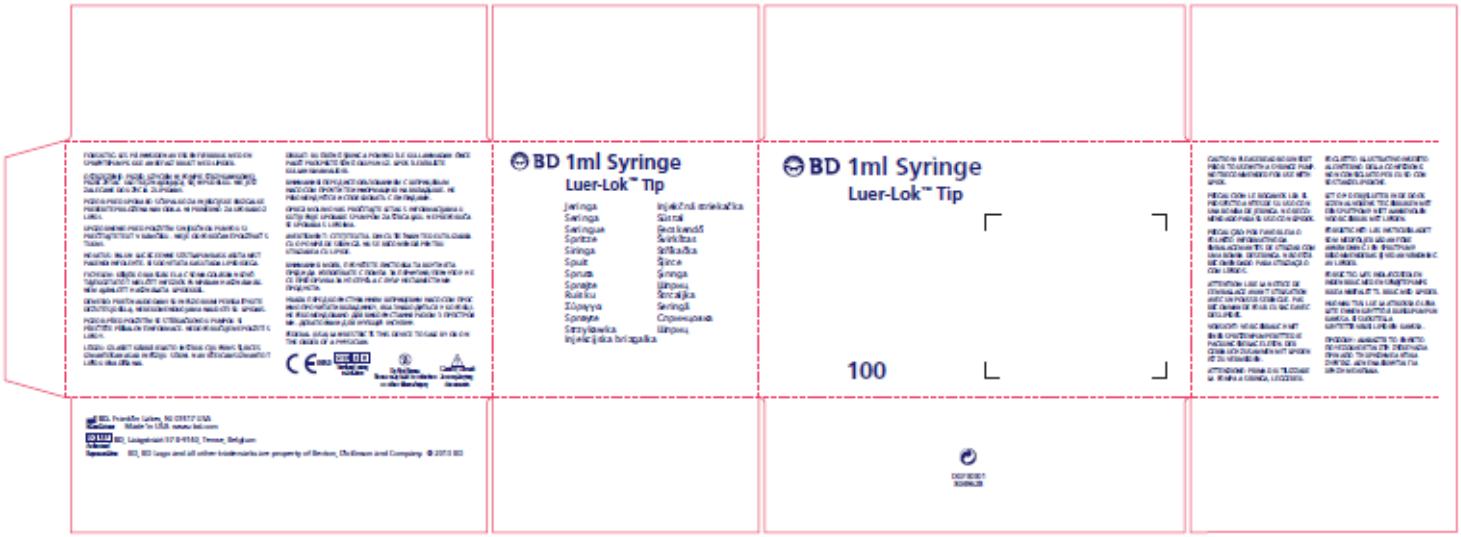
*Shelf box graphics*

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