

BD Microlance™ 3 hypodermic Needles Sterile, Single-use

BD Switzerland Sàrl
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TDS number: V201-007 – Rev.06
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1. General Information

1.1 Intended use

BD Microlance™ 3 hypodermic Needles are a single-use medical device intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines.

1.2 General description

BD Microlance™ 3 Needles consist of a colored plastic part called barrel to which a metal part called cannula, with a beveled tip, is attached using epoxy resin bonding agent. The external wall of the cannula is lubricated with silicone oil for ease of penetrability. The ensemble is protected with a plastic part called the protector.

The range of products is as follows:



Figure 1: BD Microlance™ 3 Needles

BD Catalog Number	BD Product Description	Gauge Size	Color Code	Length (mm)	Length (inch)	Wall	Bevel
300637 ²	BD Microlance™ 3 Needle 16GA 1-1/2IN	16G	White	40	1 ½"	Regular wall ²	Regular bevel
304622 ¹	BD Microlance™ 3 Needle 18GA 1-1/2IN	18G	Pink	40	1 ½"	Thin wall	Short bevel
301900 ¹	BD Microlance™ 3 Needle 18GA 2IN	18G	Pink	50	2"	Regular wall	Short bevel
301700 ¹	BD Microlance™ 3 Needle 19GA 1IN	19G	Cream	25	1"	Thin wall	Regular bevel
301500 ¹	BD Microlance™ 3 Needle 19GA 1-1/2IN	19G	Cream	40	1 ½"	Thin wall	Regular bevel
301750 ¹	BD Microlance™ 3 Needle 19GA 2IN	19G	Cream	50	2"	Thin wall	Regular bevel
304827 ¹	BD Microlance™ 3 Needle 20GA 1IN	20G	Yellow	25	1"	Thin wall	Regular bevel
301300 ¹	BD Microlance™ 3 Needle 20GA 1-1/2IN	20G	Yellow	40	1 ½"	Thin wall	Regular bevel
304434 ²	BD Microlance™ 3 Needle 21GA 5/8IN	21G	Green	16	5/8"	Regular wall ²	Regular bevel
301156	BD Microlance™ 3 Needle 21GA 1IN	21G	Green	25	1"	Thin wall	Regular bevel
304432	BD Microlance™ 3 Needle 21GA 1-1/2IN	21G	Green	40	1 ½"	Thin wall	Regular bevel
301155	BD Microlance™ 3 Needle 21GA 2IN	21G	Green	50	2"	Thin wall	Regular bevel
304727 ¹	BD Microlance™ 3 Needle 22GA 1IN	22G	Black	25	1"	Thin wall	Regular bevel
300900 ¹	BD Microlance™ 3 Needle 22GA 1-1/4IN	22G	Black	30	1 ¼"	Thin wall	Regular bevel
301000 ¹	BD Microlance™ 3 Needle 22GA 1-1/2IN	22G	Black	40	1 ½"	Thin wall	Regular bevel
300094 ¹	BD Microlance™ 3 Needle 22GA 2IN	22G	Black	50	2"	Regular wall	Regular bevel
300800	BD Microlance™ 3 Needle 23GA 1IN	23G	Blue	25	1"	Thin wall	Regular bevel
300700 ¹	BD Microlance™ 3 Needle 23GA 1-1/4IN	23G	Blue	30	1 ¼"	Thin wall	Regular bevel
304100 ¹	BD Microlance™ 3 Needle 24GA 1IN	24G	Purple	25	1"	Regular wall	Regular bevel
300400 ²	BD Microlance™ 3 Needle 25GA 1IN	25G	Orange	25	1"	Regular wall ²	Regular bevel
300600 ²	BD Microlance™ 3 Needle 25GA 5/8IN	25G	Orange	16	5/8"	Regular wall ²	Regular bevel
300300 ¹	BD Microlance™ 3 Needle 26GA 3/8IN	26G	Brown	10	3/8"	Regular wall	Regular bevel

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BD Catalog Number	BD Product Description	Gauge Size	Color Code	Length (mm)	Length (inch)	Wall	Bevel
303800 ¹	BD Microlance™ 3 Needle 26GA 1/2IN	26G	Brown	13	½"	Regular wall	Regular bevel
304300 ¹	BD Microlance™ 3 Needle 26GA 5/8IN	26G	Brown	16	5/8"	Regular wall	Regular bevel
300635	BD Microlance™ 3 Needle 27GA 1/2IN	27G	Grey	13	½"	Regular wall	Regular bevel
302200 ¹	BD Microlance™ 3 Needle 27GA 3/4IN	27G	Grey	19	¾"	Regular wall	Regular bevel
302809	BD Microlance™ 3 Needle 30GA 1/2IN for pharm customers*	30G	Yellow	13	½"	Regular wall	Regular bevel
304000	BD Microlance™ 3 Needle 30GA 1/2IN	30G	Yellow	13	½"	Regular wall	Regular bevel

*BD Microlance™ 3 Needle catalog number 302809 - NEEDLE 30G ½ inch has been manufactured specifically for pharmaceutical customers with higher sampling and additional inspection processes when compared with other catalog number found in the BD Microlance™ family of products.

Note: Please check BD catalog number availability in your country.

The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalog Number.

¹ Across BD, we routinely refine our product portfolio to serve our customers and patients more effectively. In our continuing effort to improve customer experience and streamline our broad product offering, we would like to inform you that the products SKUs 300094, 300300, 300700, 300900, 301000, 301300, 301500, 301700, 301750, 301900, 302200, 303800, 304100, 304300, 304727 and 304827 will be discontinued effective from the 31st December 2022. Similarly, the product SKU 304622 will be discontinued effective from 31st March 2023. For more information on the end date of the sales in your country, please contact your BD sales representative.

These products (except SKU 300300) will be replaced by alternatives, as described in the table below. These are direct replacements with the same intended use.

Discontinued code	Product description	Substitute code	Substitute code Description
304622	BD Microlance™ 3 Needle 18GA 1-1/2IN	303262	BD Microlance™ 3 Needle 18GA 1-1/2IN
301900	BD Microlance™ 3 Needle 18GA 2IN	310205	BD Microlance™ 3 Needle 18GA 2IN
301700	BD Microlance™ 3 Needle 19GA 1IN	303262	BD Microlance™ 3 Needle 18GA 1-1/2IN
301500	BD Microlance™ 3 Needle 19GA 1-1/2IN	303262	BD Microlance™ 3 Needle 18GA 1-1/2IN
301750	BD Microlance™ 3 Needle 19GA 2IN	310205	BD Microlance™ 3 Needle 18GA 2IN
304827	BD Microlance™ 3 Needle 20GA 1IN	301156	BD Microlance™ 3 Needle 21GA 1IN
301300	BD Microlance™ 3 Needle 20GA 1-1/2IN	304432	BD Microlance™ 3 Needle 21GA 1-1/2IN

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Discontinued code	Product description	Substitute code	Substitute code Description
304727	BD Microlance™ 3 Needle 22GA 1IN	300800	BD Microlance™ 3 Needle 23GA 1IN
300900	BD Microlance™ 3 Needle 22GA 1-1/4IN	300800	BD Microlance™ 3 Needle 23GA 1IN
301000	BD Microlance™ 3 Needle 22GA 1-1/2IN	303273	BD Microlance™ 3 Needle 23GA 1-1/2IN
300094	BD Microlance™ 3 Needle 22GA 2IN	303273	BD Microlance™ 3 Needle 23GA 1-1/2IN
300700	BD Microlance™ 3 Needle 23GA 1-1/4IN	300800	BD Microlance™ 3 Needle 23GA 1IN
304100	BD Microlance™ 3 Needle 24GA 1IN	300400	BD Microlance™ 3 Needle 25GA 1IN
300300	BD Microlance™ 3 Needle 26GA 3/8IN	N/A	N/A
303800	BD Microlance™ 3 Needle 26GA 1/2IN	300635	BD Microlance™ 3 Needle 27GA 1/2IN
304300	BD Microlance™ 3 Needle 26GA 5/8IN	300635	BD Microlance™ 3 Needle 27GA 1/2IN
302200	BD Microlance™ 3 Needle 27GA 3/4IN	300600	BD Microlance™ 3 Needle 25GA 5/8IN

The alternative products SKUs 303262, 303273 and 310205, described in the table below, are new product configurations. These alternative products are sold sterile, single-use.

BD Catalog Number	BD Product Description	Gauge Size	Color Code	Length (mm)	Length (inch)	Wall	Bevel
303262	BD Microlance™ 3 Needle 18GA 1-1/2IN	18G	Pink	40	1 ½"	Thin wall	Regular bevel
310205	BD Microlance™ 3 Needle 18GA 2IN	18G	Pink	50	2"	Thin wall	Regular bevel
303273	BD Microlance™ 3 Needle 23GA 1-1/2IN	23G	Blue	40	1 ½"	Thin wall	Regular bevel

² BD will standardize the needles between 16 G and 25 G to be thin-wall (TW) needles, while the 27 G and 30 G needles which remain unchanged (regular wall). Therefore, as of the 30th of September 2022, the products SKUs 300400, 300600, 300637 and 304434 will be manufactured with thin walls. There is not impact on the product conformity.

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)
300094 300300 300400 300600 300635 300637 300700 300800 300900 301000 301155 301156 301300 301500 301700 301750 301900 302200 302809 303262 303273 303800 304000 304100 304300 304432 304434 304622 304727 304827 310205	Address: Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain ISO 13485 Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0006 CP	Address: Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain ISO 13485 Certificate No.: 2015 05 0047 EN	N/A

1.4 Materials

Component	Material
Hub	Polypropylene and colorants
Shield piece	Polypropylene
Cannula	Stainless steel (Chromium 18-20%; Nickel 8-12%; Manganese 2%; Silicon 1%)
Adhesive	Epoxy resin
Lubricant	Medical grade Silicone oil

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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.

For products SKUs 300094, 300300, 300400, 300600, 300635, 300637, 300700, 300800, 300900, 301000, 301155, 301156, 301300, 301500, 301700, 301750, 301900, 302200, 302809, 303800, 304000, 304100, 304300, 304432, 304434, 304622, 304727 and 304827:

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 28 March 2022, BD has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzenedicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS# 68648-93-1), - Benzyl butyl phthalate (BBP) (CAS# 85-68-7), - Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), - Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), - Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), - Dibutyl phthalate (DBP) (CAS# 84-74-2), - Diisobutyl phthalate (DIBP) (CAS# 84-69-5), - Diisopentyl phthalate (DIPP) (CAS# 605-50-5), - Dipentyl phthalate (DPP) (CAS# 131-18-0), - N-pentyl-isopentyl phthalate (CAS# 776297-69-9), or - Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the article and packaging with the product numbers as referenced above, in an individual concentration above 0.1% w/w.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 28 March 2022, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 28 March 2022, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the article and packaging with the product numbers as referenced above, in an individual concentration above 0.1% (w/w). For all SKUs except SKU 404727: Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material used in the adhesive. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Substances of animal origin BSE/TSE	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. This product is manufactured using polymer resins which may contain very small amounts of stearic acid 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 ISO 22442-1:2020 and Section 6 of EMA 410/01 Rev. 3.

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	Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, 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, MDR 2017/745, and EU No 722/2012).
Polyvinyl chloride (PVC)	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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 28 March 2022, BD has not identified any chemicals in the article and packaging with the product number 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 08 July 2021 according to Art. 59 (1,10) of the Regulation (EC) No 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 BD Microlance™ 3 Needles are sterilized using a gas mixture of Ethylene Oxide and CO₂ (in the proportion 90:10). The sterilization process is validated as per EN ISO 11135-1: "Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices". ETO residues are within applicable regulations.

Data to support re-sterilization of these products by the customer is available through customer quality agreement with BD. The customer is responsible for validation of their own sterilization processes ensuring that the parameters used are not harsher than those defined by BD.

1.9 Shelf life and storage conditions

The BD Microlance™ 3 Needles shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

BD Microlance™ 3 Needles have a shelf life of 5 years.

Note:

- Processing by the user, such as re-sterilization, might impact the shelf life of the product(s).
- BD recommends to store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity (EU_DoC_BD_Microlance_Needles_Rev_13) linked to the CE certificate number 95 06 0006 CP:

Standards	
EN 556-1:2001/ AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 10993 Series	Biological evaluation of medical devices - Part 1 : 2009/ AC :2010 Evaluation and testing within a risk management process - Part 7: 2008 /AC: 2009 Ethylene oxide sterilization residuals
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods - Part 2:2009 Test of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2016	"Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements"
EN ISO 6009:2016	Sterile hypodermic needles for single use. Identification color coding
EN ISO 7864:2016	Sterile hypodermic needles for single use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: 2013 Test for irritation and skin sensitization
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices

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

BD Microlance™ 3 Needles are Class IIa Medical Devices, under Rule 6 of Annex IX of the Medical Device Directive 93/42/EEC as amended.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Microlance™ 3 Needles are referenced as follows:

- GMDN Code: 59230
- GMDN Term: Hypodermic needle, single-use

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the 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 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact 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.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
300637	BD Microlance™ 3 Needle 16GA 1-1/2IN	1	100	5000	No
304622	BD Microlance™ 3 Needle 18GA 1-1/2IN	1	100	5000	No
303262	BD Microlance™ 3 Needle 18GA 1-1/2IN	1	100	5000	No
301900	BD Microlance™ 3 Needle 18GA 2IN	1	100	4000	No
310205	BD Microlance™ 3 Needle 18GA 2IN	1	100	4000	No
301700	BD Microlance™ 3 Needle 19GA 1IN	1	100	5000	No
301500	BD Microlance™ 3 Needle 19GA 1-1/2IN	1	100	5000	No
301750	BD Microlance™ 3 Needle 19GA 2IN	1	100	4000	No
304827	BD Microlance™ 3 Needle 20GA 1IN	1	100	5000	No
301300	BD Microlance™ 3 Needle 20GA 1-1/2IN	1	100	5000	No
304434	BD Microlance™ 3 Needle 21GA 5/8IN	1	100	5000	No
301156	BD Microlance™ 3 Needle 21GA 1IN	1	100	5000	No
304432	BD Microlance™ 3 Needle 21GA 1-1/2IN	1	100	5000	No
301155	BD Microlance™ 3 Needle 21GA 2IN	1	100	4000	No
304727	BD Microlance™ 3 Needle 22GA 1IN	1	100	5000	No
300900	BD Microlance™ 3 Needle 22GA 1-1/4IN	1	100	5000	No
301000	BD Microlance™ 3 Needle 22GA 1-1/2IN	1	100	5000	No
300094	BD Microlance™ 3 Needle 22GA 2IN	1	100	4000	No
300800	BD Microlance™ 3 Needle 23GA 1IN	1	100	5000	No
303273	BD Microlance™ 3 Needle 23GA 1-1/2IN	1	100	5000	No
300700	BD Microlance™ 3 Needle 23GA 1-1/4IN	1	100	5000	No
304100	BD Microlance™ 3 Needle 24GA 1IN	1	100	5000	No
300400	BD Microlance™ 3 Needle 25GA 1IN	1	100	5000	No
300600	BD Microlance™ 3 Needle 25GA 5/8IN	1	100	5000	No
300300	BD Microlance™ 3 Needle 26GA 3/8IN	1	100	5000	No
303800	BD Microlance™ 3 Needle 26GA 1/2IN	1	100	5000	No
304300	BD Microlance™ 3 Needle 26GA 5/8IN	1	100	5000	No
300635	BD Microlance™ 3 Needle 27GA 1/2IN	1	100	5000	No
302200	BD Microlance™ 3 Needle 27GA 3/4IN	1	100	5000	No
302809	BD Microlance™ 3 Needle 30GA 1/2IN for pharm customers	1	100	5000	No
304000	BD Microlance™ 3 Needle 30GA 1/2IN	1	100	5000	No

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

2.2 Packaging material

Component	Material
Unit Pack	Paper: medical use paper 60gr/m ² Film: Polyamide/Polyethylene
Shelf Box	Carton
Shipping Case	Corrugated carton

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2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging (Top web) extracted from document DGW920 related to reference 300800:



Primary Packaging Label extracted from document 10000460010 related to reference 300800:

23G x 1"- Nr.16
(0.6 x 25mm)

REF 300800

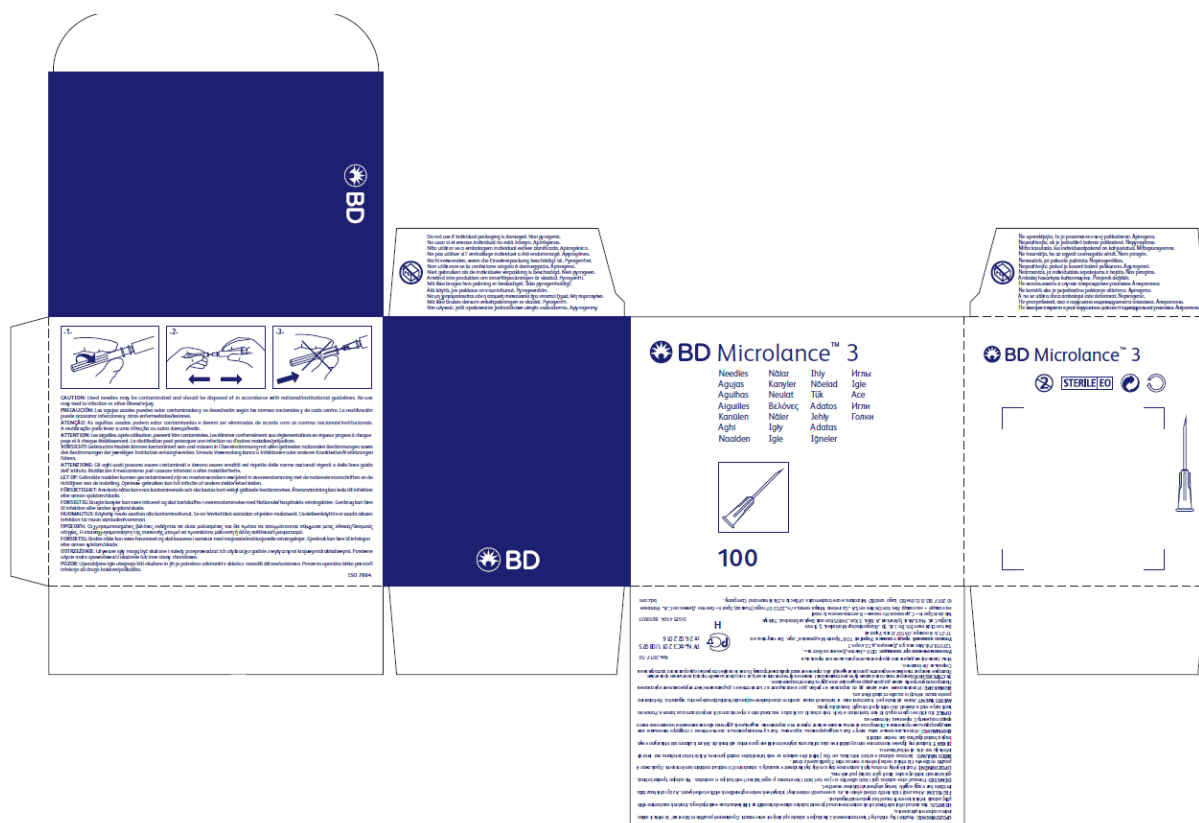


(01)00382903008001

YYYY-MM

LOT 123456

Shelf Box extracted from document DGF341 related to reference 300800:



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Shelf Box label extracted from document DGL1817 related to reference 300800:



Shipping Case extracted from document DGC174 related to reference 300800:



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Case Label extracted from document DGL1818 related to reference 300800:



REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.1: Intended use Update of 1.3: Certification Update of 1.10: Standards Update of 2.3: Examples of labeling
03	Update of 1.3: Certification
04	Addition of SKU 302809 Update of 1.2 General description Update of 1.3 Certification Update of 1.5 Materials of concern Update of 1.6 REACH information Update of 1.10 Standards Update of 2.1 Packaging configuration Update of 2.2 Packaging material Update of 2.3 Examples of labelling
05	Update of: • 1.1 Intended use • 1.2 General description • 1.3 Certification • 1.5 Materials of concern • 1.6 REACH information • 1.8 Sterilization method • 1.9 Shelf life and storage conditions • 1.10 Standards • 1.11 Classification • 1.12 GMDN code • 2.1 Packaging configuration • 2.3 Examples of labeling
06	Updated of the products descriptions in Parts 1.2 General description and 2.1 Packaging configuration, to add the wording "BD" before "Microlance™ 3 Needle". In Part 1.2 General description, change of the manufacturing end date of SKU 304622 from 12/31/2022 to 03/31/2023. In Part 2.1 Packaging configuration, change the order of the products in the table, to arrange the products by gauge and then by needle length.