Document Number: EMEA-SOP039-F1	Rev. Lev.: 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

BD® Microlance™ 3 Needles
Sterile, Single-use
Product codes:
300400 – 300600 – 300635 – 300637 – 300800
301155 – 301156 – 302809 – 303262 – 303273
304000 – 304432 – 304434 – 310205

Becton Dickinson S.A.
Carretera de Mequinenza s/n
22520 Fraga (Huesca), Spain

TDS number: V201-007 – Rev. 08
Veeva Vault Number: BD-140611
2024-November

1. General Information

1.1 Intended purpose

BD® Microlance™ 3 Needles (SKUs: 300400, 300600, 300635, 300637, 300800, 301155, 301156, 302809, 303262, 303273, 304000, 304432, 304434, 310205) 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 Intended User

BD® Microlance™ 3 Needles are intended to be used by medical practitioners (e.g. physicians, nurses, pharmacists) experienced in the use of the device. Experience levels will be from novice to expert.

1.3 General Medical Devices 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	Wall	Bevel
300637	BD® Microlance™ 3 Needle 16G x 1-1/2" (1.6 × 40 mm)	16G	White	1 ½" 40 mm	Thin	Regular
303262	BD® Microlance™ 3 Needle 18G x 1-1/2" (1.2 × 40 mm)	18G	Pink	1 ½" 40 mm	Thin	Regular
310205	BD® Microlance™ 3 Needle 18G x 2" (1.2 × 50 mm)	18G	Pink	2" 50 mm	Thin	Regular
304434	BD® Microlance™ 3 Needle 21G x 5/8" (0.8 × 16 mm)	21G	Green	5/8" 16 mm	Thin	Regular
301156	BD® Microlance™ 3 Needle 21G x 1" (0.8 × 25 mm)	21G	Green	1" 25 mm	Thin	Regular
304432	BD® Microlance™ 3 Needle 21G x 1-1/2" (0.8 × 40 mm)	21G	Green	1 ½" 40 mm	Thin	Regular
301155	BD® Microlance™ 3 Needle 21G x 2" (0.8 × 50 mm)	21G	Green	2" 50 mm	Thin	Regular
303273	BD® Microlance™ 3 Needle 23G x 1-1/2" (0.6 × 40 mm)	23G	Blue	1 ½" 40 mm	Thin	Regular
300800	BD® Microlance™ 3 Needle 23G x 1" (0.6 × 25 mm)	23G	Blue	1" 25 mm	Thin	Regular
300400	BD® Microlance™ 3 Needle 25G x 1" (0.5 × 25 mm)	25G	Orange	1" 25 mm	Thin	Regular
300600	BD® Microlance™ 3 Needle 25G x 5/8" (0.5 × 16 mm)	25G	Orange	5/8" 16 mm	Thin	Regular
300635	BD® Microlance™ 3 Needle 27G x ½" (0.4 × 13 mm)	27G	Grey	½" 13 mm	Regular	Regular
302809*	BD® Microlance™ 3 Needle 30G x ½" (0.3 × 13 mm)	30G	Yellow	½" 13 mm	Regular	Regular
304000	BD® Microlance™ 3 Needle 30G x ½" (0.3 × 13 mm)	30G	Yellow	½" 13 mm	Regular	Regular

*BD® Microlance™ 3 Needle 30G x ½" (0.3 × 13 mm) (BD catalog number 302809) 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.

1.4 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)
300400 300600 300635 300637 300800 301155 301156 302809 303262 303273 304000 304432 304434 310205	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	CE certified with AEMP (0318) MDD Certificate No.:95 06 0006 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	N/A

1.5 UDI-DI and Basic UDI-DI

The products with the catalogue numbers referenced above are CE certified under Medical Device Directive (MDD). BD is transitioning to Medical Device Regulation (MDR), and as the information in this section is the requirement of MDR, it is still not available. The TDS will be updated once the transition to MDR is completed.

1.6 Materials

Component	Material
Hub	Polypropylene and colorants
Shield	Polypropylene
Cannula	Stainless steel
Adhesive	Epoxy resin
Lubricant	Silicone oil

1.7 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 the product SKUs listed in this Technical Data Sheet:

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 July 2024, 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 articles 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 11 July 2024, 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 11 July 2024, BD has not identified any • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% (w/w). 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. These products are 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. 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, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical devices (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, 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.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 July 2024, 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 14 June 2023 according to Art. 59 (1,10) of the Regulation (EC) No 1907/2006 (REACH).

1.9 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.

1.10 Sterilization method

This catalogue numbers are sterilized using a gas mixture of Ethylene Oxide and CO2 (in the proportion 90:10). Sterilization process is validated according to EN ISO 11135 "Sterilization of healthcare products-Ethylene oxide-: Requirements for development, validation and routine control of a sterilization process for medical devices".

1.11 Shelf life and storage conditions

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.

1.12 Applied Standards

As per extract from the Technical Documentation for **BD® Microlance™ 3 Needles** on the Technical File (DT-003) and on the Declaration of Conformity (EU_DoC_BD_Microlance_Needles_Rev_17) linked to EC certificate number 95 06 0006 CP for the SKUs listed in this TDS:

Standard reference number	Title
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
EN ISO 11737-2:2019	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

Standard reference number	Title
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.

1.13 Classification

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

1.14 Medical Device Nomenclature

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), the SKUs listed in this TDS, are referenced as follows:

BD® Microlance™ 3 Needles (SKUs: 300400, 300600, 300635, 300637, 300800, 301155, 301156, 302809, 303262, 303273, 304000, 304432, 304434, 310205):

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

1.15 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.

1.16 Other information

- 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 are 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 16G x 1-1/2" (1.6 × 40 mm)	1	100	5000	No
303262	BD® Microlance™ 3 Needle 18G x 1-1/2" (1.2 × 40 mm)	1	100	5000	No
310205	BD® Microlance™ 3 Needle 18G x 2" (1.2 × 50 mm)	1	100	4000	No
304434	BD® Microlance™ 3 Needle 21G x 5/8" (0.8 × 16 mm)	1	100	5000	No
301156	BD® Microlance™ 3 Needle 21G x 1" (0.8 × 25 mm)	1	100	5000	No
304432	BD® Microlance™ 3 Needle 21G x 1-1/2" (0.8 × 40 mm)	1	100	5000	No
301155	BD® Microlance™ 3 Needle 21G x 2" (0.8 × 50 mm)	1	100	4000	No
300800	BD® Microlance™ 3 Needle 23G x 1" (0.6 × 25 mm)	1	100	5000	No
303273	BD® Microlance™ 3 Needle 23G x 1-1/2" (0.6 × 40 mm)	1	100	5000	No
300400	BD® Microlance™ 3 Needle 25G x 1" (0.5 × 25 mm)	1	100	5000	No
300600	BD® Microlance™ 3 Needle 25G x 5/8" (0.5 × 16 mm)	1	100	5000	No
300635	BD® Microlance™ 3 Needle 27G x ½" (0.4 × 13 mm)	1	100	5000	No
302809	BD® Microlance™ 3 Needle 30G x ½" (0.3 × 13 mm)	1	100	5000	No
304000	BD® Microlance™ 3 Needle 30G x ½" (0.3 × 13 mm)	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

2.3 Recycled material in packaging

-Recyclability of Packaging:

Based on our ongoing data collection and/or information received from our suppliers, the secondary and tertiary portions of the packaging of the medical devices referenced above are recyclable (at least partially) according to EN 13430:2004. Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities.

-Recycled Content:

BD Product Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
303262	Unknown	Unknown
300637	Unknown	Unknown
301156	Unknown	Unknown
300400	Unknown	Unknown
303273	Unknown	Unknown
300600	Unknown	Unknown
300800	Unknown	Unknown
304432	Unknown	Unknown
310205	Unknown	Unknown
302809	Unknown	Unknown
302635	Unknown	Unknown
304000	Unknown	Unknown
301155	Unknown	Unknown
304434	Unknown	Unknown

2.4 Examples of labeling

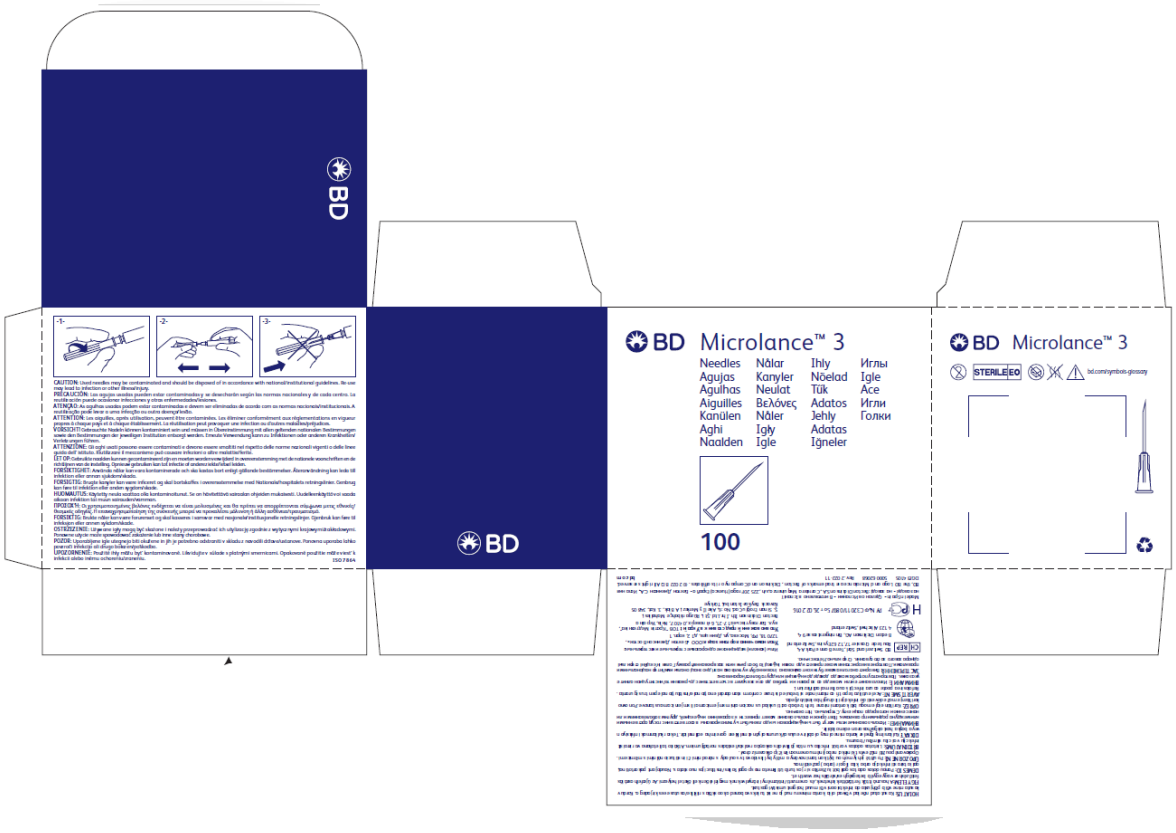
According to European Medical Device directive, labels are multilingual.

Labeling for BD® Microlance™ 3 Needle 23G x 1" (0.6 x 25 mm) (SKU: 300800):

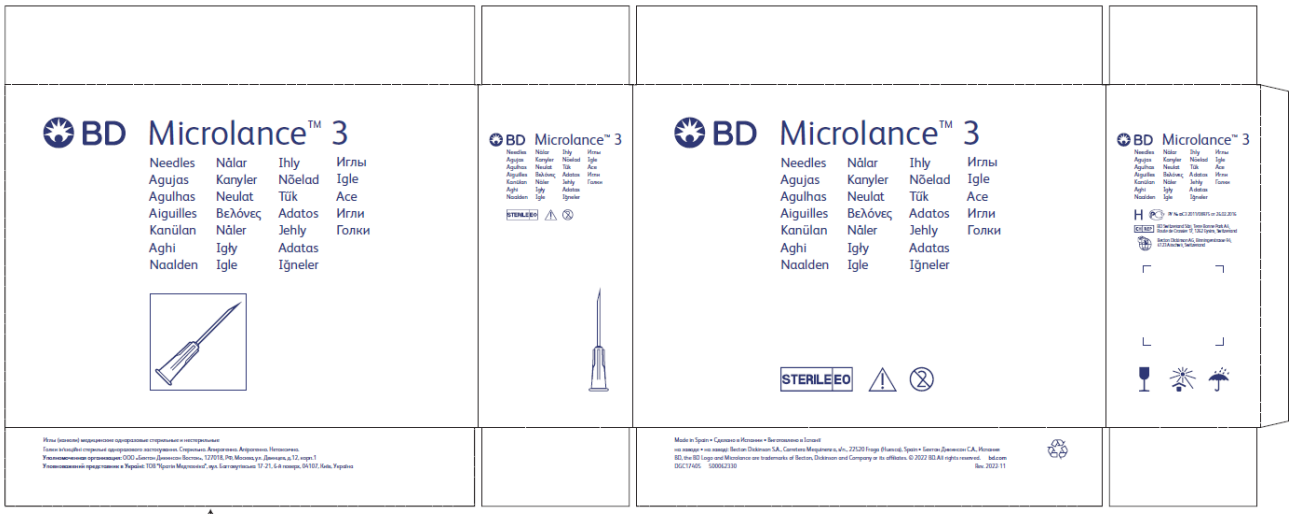
Primary Packaging (Top Web) extracted from document DGW920 (Rev.04) and 10000460010 (Rev.01) related to reference 300800:

Shelf Box label extracted from document DGL1817 (Rev.02) related to reference 300800:

Shelf Box extracted from document DGF341 (Rev.05) related to reference 300800:



Shipping Case extracted from document DGC174 (Rev.05) related to reference 300800:



Case Label extracted from document DGL1818 (Rev.02) related to reference 300800:

REVISION	CHANGE SUMMARY
01	Initial release according to new TDS 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.
07	Release according to new template 1.3 Certification: change of ISO 13485 certification
08	Remove the following product codes: 300094, 300300, 300700, 300900, 301000, 301300, 301500, 301700, 301750, 301900, 302200, 303800, 304100, 304300, 304622, 304727, 304827. Release according to new template: EMEA-SOP039-F1 as per technical file number: • DT-003, version 34 published on April 1st 2024