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

BD® Blunt Fill Needle
Sterile, Single-use
Product codes: 303129

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

BD® Blunt Fill Needle
Sterile, Single-use
Product codes: 305181

Becton, Dickinson and Company
1 Becton Drive Franklin Lakes
New Jersey 07417, USA

BD® Blunt Fill Needle-Filter
Sterile, Single-use
Product codes: 305211

TDS number: V201-013 – Rev. 04
Veeva Vault Number: BD-140613
2024-December

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1. General Information

1.1 Intended purpose

BD® Blunt Fill Needles (SKUs: 303129, 305181) and BD® Blunt Fill Needle-Filter (SKU: 305211) are used for aspiration of fluids from vials and ampoules. The BD® Blunt Fill Needles and BD® Blunt Fill Needle-Filter are not intended for skin injections.

1.2 Intended User

BD® Blunt Fill 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. Minimal or no training is required for operation of BD® Blunt Fill Needles.

BD® Blunt Fill Needle – Filter is to be used by medical practitioners (e.g., physicians, nurses, nurse practitioner, pharmacists) experienced in use of the device.

1.3 General Medical Devices description

BD® Blunt Fill Needles and BD® Blunt Fill Needle-Filter consist of a hollow needle with blunt tip, a needle hub, and a needle shield.

- **BD® Blunt Fill Needles (SKUs: 303129, 305181)** have female luer fittings, which mate to male luer fittings.
- **BD® Blunt Fill Needle-Filter 18G x 1 ½" (1.2 x 40 mm) (SKU: 305211)** has a 5-micron filter to filter out particles such as, glass and plastic fragments.

BD® Blunt Fill Needles and **BD® Blunt Fill Needle-Filter** are single-use medical devices, sold to healthcare professionals, specifically designed to reduce the risk for needlestick injuries during medication preparation.

Figure 1: BD® Blunt Fill Needle-Filter (in lilac) and BD® Blunt Fill Needle (in red)

BD Catalog Number	BD Product Description	Gauge Size	Color Code	Length	Wall	Bevel	Filter
303129	BD® Blunt Fill Needle 18G x 1-1/2" (1.2 × 40 mm)	18G	Red	1 ½" 40 mm	Thin	Blunt	N/A
305181	BD® Blunt Fill Needle 18G x 1" (1.2 × 25 mm)	18G	Red	1" 25 mm	Thin	Blunt	N/A
305211*	BD® Blunt Fill Needle-Filter 18G x 1-1/2" (1.2 × 40 mm)	18G	Lilac	1 ½" 40 mm	Regular	Blunt	5-micron filter

* Intraocular use is not validated by BD.

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)
303129	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	CE certified with AEMPS (0318) Certificate No.: 2015 03 0838 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: MD 778144	N/A

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)
305181 305211	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 USA **ISO 13485** Certificate No.: MD19.2305	CE certified by NSAI (0050) Certificate No.: 252.308	**Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 USA **ISO 13485** Certificate No.: MD19.2143	Becton Dickinson, Laagstraat 57, B-9140 Temse, Belgium

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	**BD® Blunt Fill Needles (SKUs: 303129, 305181)**: polypropylene + colorant **BD® Blunt Fill Needle-Filter (SKU 305211)**: polycarbonate + colorant
Cannula	Stainless steel
Shield	Polypropylene + colorant
Adhesive	Epoxy
Lubricant	Silicone
Filter	**BD® Blunt Fill Needle-Filter (SKU 305211):** Plastic membrane filter (5 micron)

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 25 June 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),

Material	Comment
	• 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 25 June 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 25 June 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 25 June 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

BD® Blunt Fill Needle (SKU 303129) is 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".

BD® Blunt Fill Needle (SKU: 305181) and BD® Blunt Fill Needle-Filter (SKU: 305211) are sterilized using radiation. The sterilization process is validated per EN ISO 11137-1 (Sterilization of Health Care Products - Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices).

1.11 Shelf life and storage conditions

The products listed in this Technical Data Sheet, shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
The products listed in this Technical Data Sheet, 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® Blunt Fill Needle** on the Technical File (DT-016) and on the Declaration of Conformity (EU_DoC_BD_Blunt_Fill_Needle_Rev_11) linked to EC certificate number 2015 03 0838 CP for **SKU: 303129.**

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
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"

Standard reference number	Title
EN 1707:1996	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment - Lock Fittings
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN ISO 11138-2:2017	Sterilization pf health care products – Biological Indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
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
UNE EN ISO 80369-7:2022	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

As per extract from the Technical Documentation for **BD® Blunt Fill Needles** and **BD® Blunt Fill Needle-Filter** on the Technical File (DT-016) and on the Declaration of Conformity (EU_DoC_BD_Blunt_Fill_Needle_Rev_11) linked to EC certificate number 2015 03 0838 CP for **SKUs: 305211** and **305181.**

Standard reference number	Title
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
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 1707:1996	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment - Lock Fittings
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 11737-1:2018	Sterilization of medical devices – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products
EN ISO 11737-2:2019	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2:2017	Sterilization pf health care products – Biological Indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

Standard reference number	Title
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 14155:2020	Clinical investigation of medical devices for human subjects. Good clinical practice
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
UNE EN ISO 80369-7:2022*	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ISO 80369-20:2015*	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
IEC 62366-1:2015+AMD2020	Medical devices — Part 1: Application of usability engineering to medical devices
EN ISO 10993 series	Biological evaluation of medical devices

*This standard is only applicable for SKU: 305181. These products contain ISO 80369 compliant hubs.

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® Blunt Fill Needle (SKU 303129) is a Class I sterile Medical Device under Rule 2 of Annex IX of the Medical Devices Directive 93/42/EEC.

BD® Blunt Fill Needle (SKU 305181) and BD® Blunt Fill Needle-Filter (SKU: 305211) are Class I sterile Medical Devices under Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC.

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:

For BD® Blunt Fill Needles (SKUs 303129, 305181):

- GMDN Code: 16627
- GMDN Term: Medication transfer needle, non-filtering/non-vented

For BD® Blunt Fill Needle-Filter (SKU 305211):

- GMDN Code: 16266
- GMDN Term: Medication transfer needle, filtering

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*
303129	BD® Blunt Fill Needle 18G x 1-1/2" (1.2 × 40 mm)	1	100	5000	No
305181	BD® Blunt Fill Needle 18G x 1" (1.2 × 25 mm)	1	100	1000	No
305211	BD® Blunt Fill Needle-Filter 18G x 1-1/2" (1.2 × 40 mm)	1	100	1000	No

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

2.2 Packaging material

Component	Material
Unit Pack	For **SKU 303129:** Top Web: Polyamide/Polyethylene Bottom Web: Paper For **SKUs 305211, 305181:** Top web: Paper Bottom web: Thermoformable plastic
Shelf Box	Corrugated 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 Catalogue Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
303129	Unknown	Unknown
305181	Unknown	Unknown
305211	Unknown	Unknown

2.4 Examples of labeling

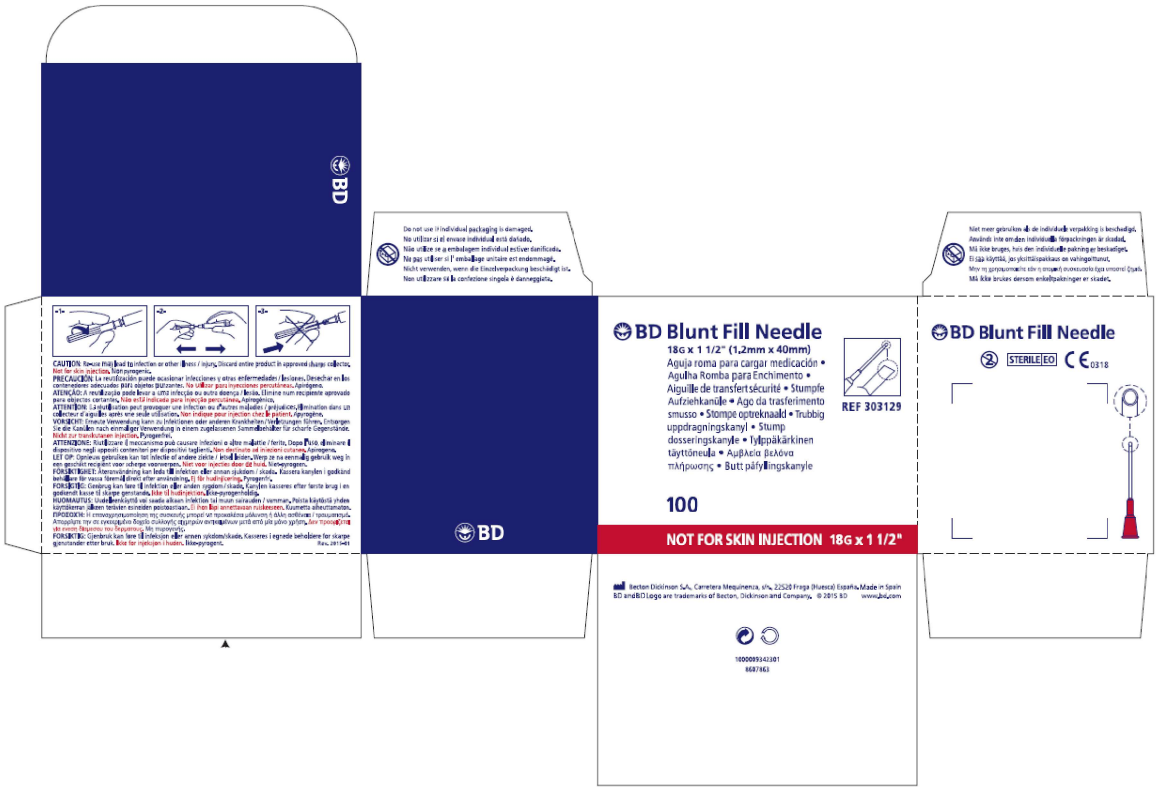
According to European Medical Device directive, labels are multilingual.

Labeling for BD® Blunt Fill Needle 18G x 1-1/2" (1.2 × 40 mm) (SKU: 303129):

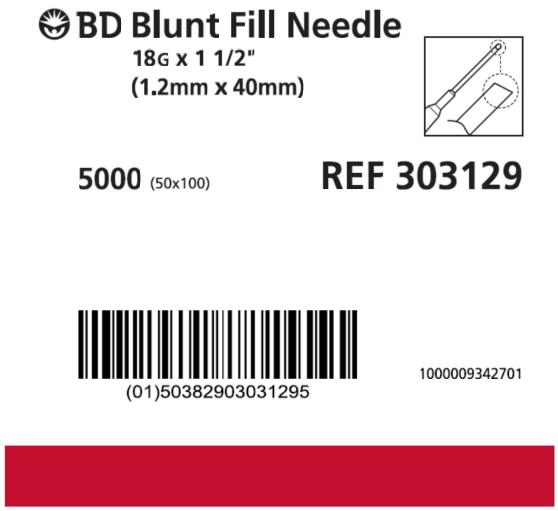
Primary Packaging (Top Web) extracted from document 10000093422 (Rev.03) related to reference 303129:

Shelf Box label extracted from document 10000093426 (Rev.01) related to reference 303129:

Shelf Box extracted from document 10000093423 (Rev.01) related to reference 303129:



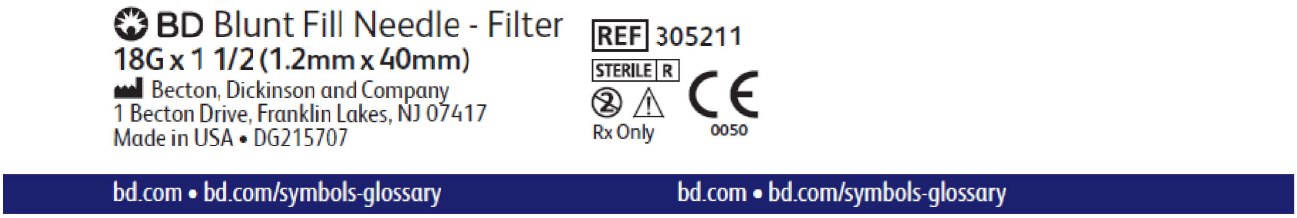
Shipping Case label extracted from document 10000093427 (Rev.01) related to reference 303129:



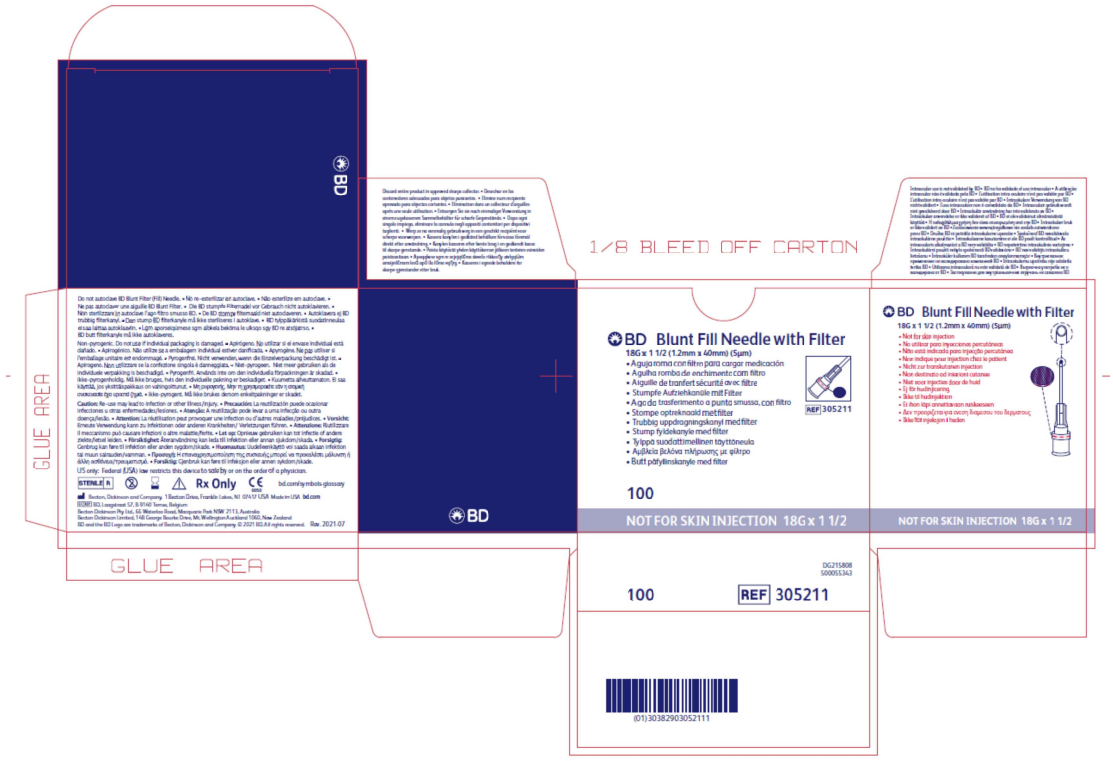
Shipping Case extracted from document 10000093424 (Rev.02) related to reference 303129:

Labeling for BD® Blunt Fill Needle-Filter 18G x 1-1/2" (1.2 x 40 mm) (SKU: 305211):

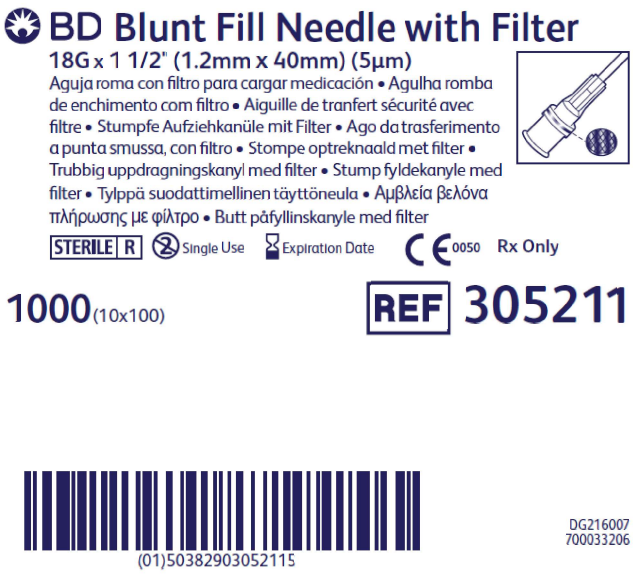
Primary Packaging (Top Web) extracted from document DG2157 (Rev.07) related to reference 305211:



Shelf Box label extracted from document DG2158 (Rev.08) related to reference 305211:



Shipping Case extracted from document DG2160 (Rev.07) related to reference 305211:



REVISION	CHANGE SUMMARY
01	Initial release according to new TDS template
02	Update to 1.4: Materials - added colorant to the needle shield material information, the information was missing in the previous version of the Technical data sheet Update to 2.3: Examples of labeling – updated to Primary Packaging Label
03	Release according to new template Correction on trademarks 1.3 Certification: new ISO certificate Update of 1.5 Material of Concern statements to better reflect the Technical File. Update of 1.10 Standards Update of 1.15 Medical Device Nomenclature with a new GMDN code
04	Remove product codes: 305180 and 305183 Release according to new template: EMEA-SOP039-F1 as per technical file number: • DT-016, version 15 published on March 27th, 2024 • DTF0006, version Q published on June 27th 2024