BD Extension Set
Sterile, for Single Use
Alaris™ Products
20350E-0006, C20350 and C20128-0006

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-112 Rev. 01
BD-104999 Rev. 01
2023-October

1. General Information

1.1 Intended use

1.1.1 Intended purpose

Extension sets are infusion administration sets providing a flexible sterile fluid path to deliver intravenous solutions. Gravity sets provide a conduit for fluids intended for intra-venous infusion enabling connection to a fluid reservoir and a venous-puncture device.

1.1.2 Intended User

The BD Secondary Sets are intended to be used by healthcare professionals who are experienced in IV therapy.

1.2 General Medical Devices description

Extension sets are add-on products to primary administration sets to lengthen and/or provide additional IV access ports, the primary administration set may or may not be administering therapy using a pump.

Figure 1: BD Extension Set

BD Catalog Number	BD Product Description	Priming Volume (ml)	Total Length (cm)	Box (units)
20350E-0006	BD Extension Set. 0.2 Micron Filter Needle Free Valve Low Sorbing	5	43	100
C20350	BD Extension Set. 0.2 MF 1 Injection Port Low Sorbing	6	51	20
C20128-0006	BD Extension Set 1.2 Micron Filter 1 Injection Port	5	48	72

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 use the BD Catalog Number.

Further features:

Product reference	Gravity Use	Pump Use	Ventilation Spike	Back Check Valve	Filter Size	Change Interval	Lipid Resistant
20350E-0006	Yes	No*	No	No	In-Line filter 0.2 micron	72h**	No
C20350	Yes	No*	No	No	In-Line filter 0.2 micron.	24h	No
C20128-0006	Yes	No*	No	No	In-Line filter 1.2 micron.	24h	No

*) Extension sets are add-on products to primary administration sets to lengthen and/or provide additional IV access ports, the primary administration set may or may not be administering therapy using a pump.
**) Note: Replace set every 72 hours or after 100 activations of Needle-Free Valve whichever occurs first.

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Sites (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
20350E-0006 C20350 C20128-0006	**Address:** BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Bâtiment A4, 1262 Eysins, Switzerland **ISO 13485** Certificate No.: MD 71300	CE certified with BSI Certificate No.: 502238	**Address:** Sistemas Medicos Alaris S.A. de C.V., Blvd. Insurgentes # 20351, Parque Industrial El Florido Seccion Vistas 1, Tijuana Baja California, CP 22244, Mexico **ISO 13485** Certificate No.: FM 688319	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland

1.4 UDI-DI

BD Catalog Number	UDI-DI
20350E-0006	Primary DI: 07613203020077
	Package Level 2 DI: 37613203020085
	Package Level 3 DI: None
C20350	Primary DI: 07613203009379
	Package Level 2 DI: 37613203009387
	Package Level 3 DI: None
C20128-0006	Primary DI: 07613203009393
	Package Level 2 DI: 37613203009400
	Package Level 3 DI: None

1.5 Eudamed Registration

Manufacturer Single Registration Number (SRN): IE-AR-000007610

- EU Authorised Representative Single Registration Number (SRN): N/A

1.6 Person Responsible for Regulatory Compliance

The information about the Person Responsible for Regulatory Compliance (PRRC) can be found on Eudamed website:

https://ec.europa.eu/tools/eudamed/#/screen/home

1.7 Materials

20350E-0006:

Component	Material
Non-vented male Luer cap	ABS
Female Luer lock	PVC (not made with DEHP)
Try-layer tubing	PVC (not made with DEHP), PE
Inline Filter 0.2 µm (adult)	Goretex, Polyethersulfone, Acrylic
Pinch clamp	ABS
SmartSite valve Y port	Acrylic, ETPU Polymer, silicone rubber, silicone fluid
Rotating male Luer	ABS, PE

C20350:

Component	Material
Non-vented male Luer cap	ABS
Female Luer lock	PVC (not made with DEHP)
Try-layer tubing	PVC (not made with DEHP), PE
Inline filter 0,2; adult, with hydrophobic and hydrophilic membrane	Goretex, Polyethersulfone, Acrylic
Pinch clamp	ABS
Long Y-Site	Acrylic, Synthetic Isoprene, PVC
Luer lock male	ABS, PE

C20128-0006:

Component	Material
Non-vented male Luer cap	ABS
Female Luer lock	PVC (not made with DEHP)
Kink Resistant tubing	PVC
Inline filter 1,2; adult, with hydrophobic and hydrophilic membrane	Goretex, Polyethersulfone, Acrylic
Pinch clamp	ABS
Long Y-Site	Acrylic, Synthetic Isoprene, PVC
Luer lock male	ABS, PE

1.8 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.

Material	Comment
Phthalates	The products in this Technical Data Sheet are not made with added DEHP or other phthalates (except the model C20128-0006).
Latex	The products are Latex Free and do not come into contact with Latex during the manufacturing process at the Mexico manufacturing site.
Bisphenol A	The products in this Technical Data Sheet do not contain Bisphenol A.
Substances of animal origin BSE/TSE	The products in this Technical Data Sheet are not made with substances of animal origin, neither BSE nor TSE.
Polyvinyl chloride (PVC)	Some parts of the products in this Technical Data Sheet are made with polyvinyl chloride, moreover not made with added DEHP (exception model C20128-0006 that is made of PVC and contains DEHP).

1.9 REACH information

The Extension Sets are within the scope of Directive 2006/121/EC. If the Extension Sets contain substances which are on the Candidate SVHC (substances of very high concern) List from 2011, BD must notify ECHA if the total amount of an SVHC contained within its annual production exceeds 1 tonne.

1.10 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.

1.11 Sterilization method

Sterilization method used for reference 20350E-0006 and C20350 is Ethylene Oxide.
Sterilization method used for reference C20128-0006 is Radiation.

1.12 Shelf life and storage conditions

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

Reference 20350E-0006, C20350 and C20128-0006 have a shelf life of 3 years.
BD recommends to store in a dry and warm place, not exposed to strong light.

1.13 Standards

As per extract from the Declaration of Conformity (STED104) linked to CE certificate number 502238:

Harmonized Standards	
BS 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.
BS EN 1041:2008 +A1:2013	Information supplied by the manufacturer with the medical devices.
BS EN ISO 1135-4:2015/Corr 2016	Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed.
BS EN ISO 1135-5:2015	Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus.
BS EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
BS EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.
BS EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
BS EN ISO 10993- 7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
BS EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
BS EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
BS EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
BS EN ISO 11137- 1:2015/A2:2019	Sterilization of health care products Radiation Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ISO 11137-2:2013/Amd1:2022	Sterilization of health care products. Radiation. Establishing the sterilization dose
BS EN ISO 11137-3:2017	Sterilization of healthcare products - Radiation Part 3: Guidance on dosimetric aspects of development, validation, and routine control
BS EN ISO 11607-1:2020+A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
BS EN ISO 11607-2:2020+A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
BS EN ISO 11737-1:2018+A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product.
BS EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process
BS EN ISO 13485:2016+A11:2021	Medical devices Quality management systems Requirements for regulatory purposes.
BS EN ISO 14971:2019+A11:2021	Medical Devices - Application of risk management to medical devices.
BS EN ISO 15223- 1:2016/AC:2017	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.
BS EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates.
BS EN 20594-1:1994	Conical fittings with a 6%(Luer) taper for syringes, needles and other certain medical equipment part 1: General requirements

Non-Harmonized Standards	
BS EN ISO 8536-4:2013 +A1:2013	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.
BS EN ISO 8536-5:2013	Infusion equipment for medical use - Part 5: Burette infusion sets for single use, gravity feed.
BS EN ISO 8536-8:2015	Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus.
BS EN ISO 8536-9:2015	Infusion equipment for medical use Part 9: Fluid lines for single use with pressure infusion equipment.
BS EN ISO 8536-10:2015	Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment.
BS EN ISO 8536-11:2015	Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment.
BS EN ISO 10993-2:2022	Biological evaluation of medical devices Part 2: Animal welfare requirements
BS EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.
BS EN ISO 10993-16:2017	Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993- 18:2020/Amd1:2022	Biological evaluation of medical devices Part 18: Chemical characterization of materials
BS EN ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration.
BS EN ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.
BS EN ISO 14644-5:2004	Cleanrooms and associated controlled environments – Part 5: Operations.
ISTA-1A - 2014 Edition	Non-Simulation Integrity Performance Tests, Packaged- Products weighing 150 lb (68 kg) or Less.
ISTA-2A - 2012 Edition	Partial-Simulation Performance Tests, Packaged-Products weighing 150 lb (68 kg) or Less.

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.

1.14 Classification

EC Product Class IIa in accordance with Council Directive 93/42/EEC, Annex IX, Rule 2.
The Extension Sets are EC Product Class IIa medical devices under EC Product Classification Rule 2.

1.15 GMDN code

GMDN Code: 12170
GMDN Term: Intravenous administration tubing extension set

1.16 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.

1.17 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)	Shipper Box (Qty)	Directions for use (DFU)
20350E-0006	BD Extension Set. 0.2 Micron Filter Needle Free Valve Low Sorbing	1	100	Yes*
C20350	BD Extension Set. 0.2 MF 1 Injection Port Low Sorbing.	1	20	Yes*
C20128-0006	BD Extension Set 1.2 Micron Filter. 1 Injection Port.	1	72	Yes*

*Peel pouch with printed Directions for Use

2.2 Packaging material

Component	Material
Web packaging	Tyvek, PET, LDPE
Ink	Printing Ink
Box	Cardboard

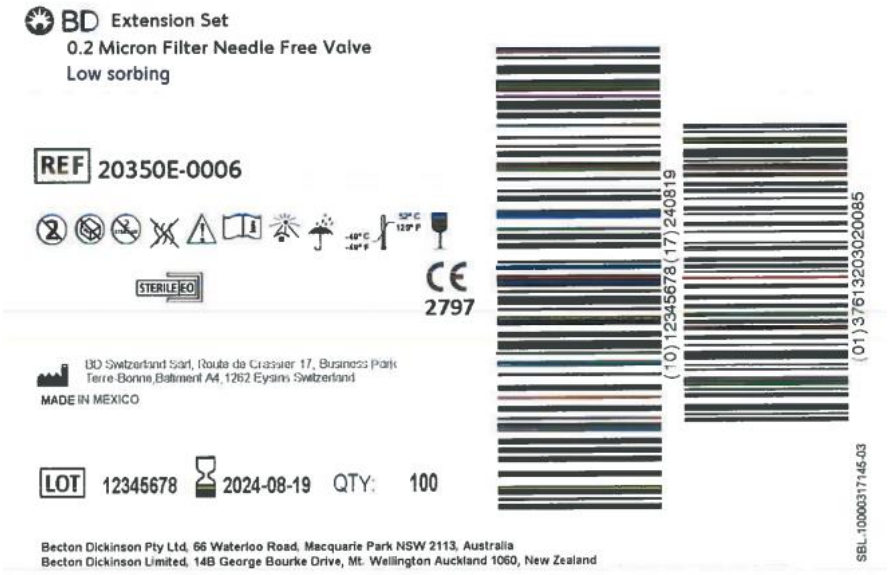
2.3 Examples of labeling

Model No.	English	Arabic	Chinese	Czech	Danish	Dutch	Estonian	Finnish	French	German	Greek	Hungarian	Italian	Latvian	Norwegian	Polish	Portuguese	Romanian	Russian	Serbian	Spanish	Slovak	Slovenian	Swedish	Turkish
20350E-0006	x			x	x	x		x	x	x	x	x	x		x	x	x	x	x		x	x	x	x	x
C20128-0006	x			x	x	x		x	x	x	x	x	x		x	x	x	x	x		x	x	x	x	x
C20350	x			x	x	x		x	x	x	x	x	x		x	x	x	x	x		x	x	x	x	x

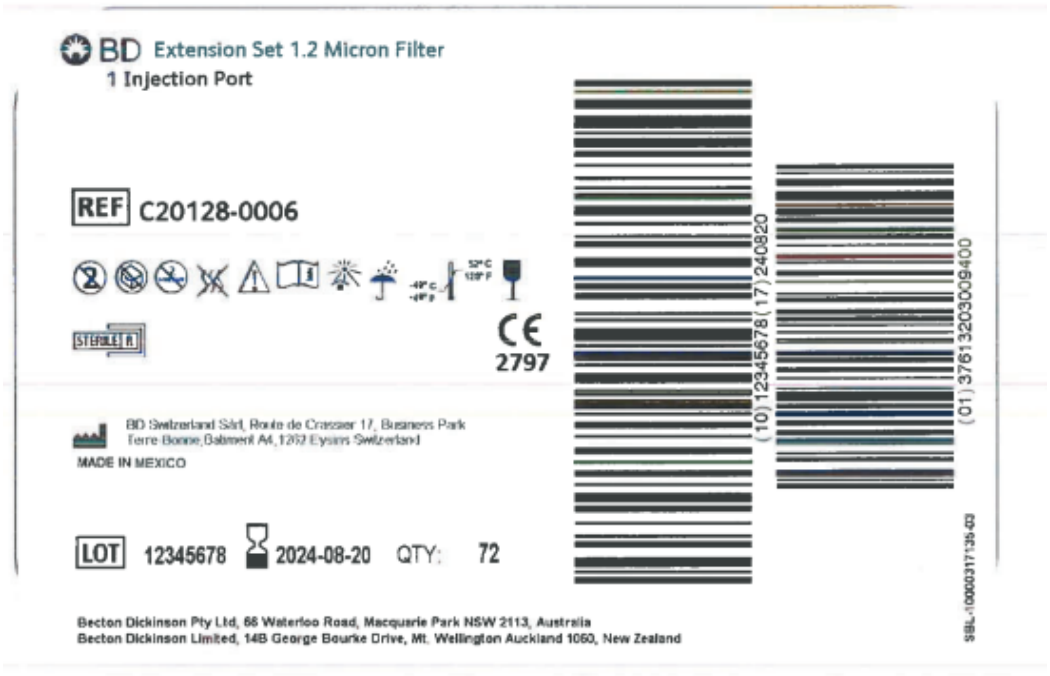
Primary Packaging Pouch extracted from document 630-01654 10000319456 related to reference 20350E-0006:

Primary Packaging Pouch Label extracted from document 10000333965-00 related to reference 20350E-0006, C20350 and C20128-0006:

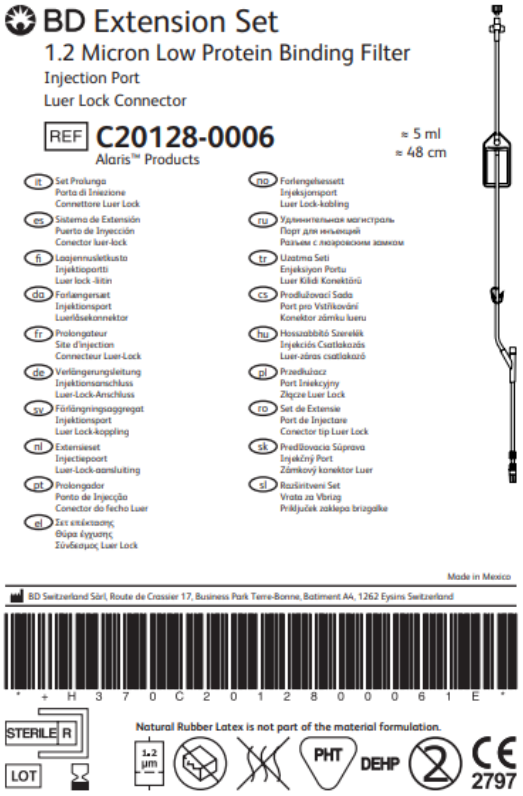
Shipper label extracted from document 10000317145 related to reference 20350E-0006:



Shipper label extracted from document 10000317135 related to reference C20128-0006:



IFU insert (English part only) extracted from document 630-01508 10000317070 related to reference C20128-0006:



en

Fluid path is STERILE and NONPYROGENIC.

Precautions:

- **Do not use if package is damaged or protector caps are unattached.**
- **Do not administer blood or blood products through filter.**
- **Reuse compromises safety and efficacy.**
- **Contains DEHP, a phthalate potentially hazardous in the prolonged treatment of children or pregnant or nursing women. Medical practitioners must balance the benefit of use of this product against foreseeable risks.**

DIRECTIONS - Use Aseptic Technique

NOTE: Replace set every 24 hours.

1. Connect extension set female luer lock to a fully primed primary infusion set or syringe.
2. Holding filter in vertical position (inlet port up), prime extension set. **DO NOT INVERT FILTER.**
   NOTE: Maintain filter at or below vascular access device.

Natural Rubber Latex is not part of the material formulation.

630-01508 Rev 01

REVISION	CHANGE SUMMARY
01	Initial release according to new template