Becton Dickinson and Company
BD Medical

Business Park Terre-Bonne,
Batiment A4,
CH-1262 Eysins
Switzerland
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TECHNICAL DATA SHEET

Infusion Administration Sets for Gravity, Vented

DEHP and natural rubber latex are not part of the material formulation
Sterile, Single Use

Product references presented in this technical data sheets:
03508411318, 03508318429

1. General Information

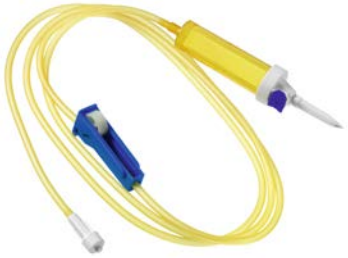
1.1 General

The products presented in this technical data sheet represent a collection of sterile devices designed to conduct fluids from the intravenous (IV) fluid container to the patient's venous system. They typically include tubing, connectors, chambers, clamps, and needleless or injection ports. This is a single-use device.

Infusion Administration Sets for Gravity presented in this technical data sheet comprise of flexible tubing not with added DEHP (in case of 03508411318 not with added PVC), drip chamber with 15 mic filter and sharp spike on one side, flow controller, male luer lock and protective cap at the other end, distal end.
There are two different models:

1) Light resistant, for light sensitive drugs, model 03508411318
2) The standard one, model 03508318429

The intended use is for gravitational intravenous administration.



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PRODUCT REFERENCE	PRODUCT DESCRIPTION	TUBE LENGTH in cm	TOTAL LENGTH in cm	BOX (UNITS)
03508411318	Infusion Administration Set, Vented, light sensitive, PVC-FREE, (with fix male luer lock)	147	155	100 (50x2)
03508318429	Infusion Administration Set, Vented, DEHP-free (with rotating male luer lock & cap with hydrophobic filter)	190	200	100 (50x2)

Further Features

PRODUCT REF.	GRAVITY USE	PUMP USE	VENTILATION SPIKE	BACK CHECK VALVE	NEEDLE-FREE CONN. SMART SITE™	FILTER SIZE	CHANGE INTERVAL	LIPID RESIST.
03508411318	Yes	No	Yes	No	No	15 nic (drip chamber)	Refer to Hospital Protocol	Yes
03508318429	Yes	No	Yes	No	No	15 nic (drip chamber)	Refer to Hospital Protocol	Yes

1.2 Certification

PRODUCT REF.	LEGAL MFG.	MFG. SITE	ISO CERT. NO.	NOTIFIED BODY	EC CERT NO.	COUNTRY OF ORIGIN
03508411318 03508318429	BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, Eysins, CH-1262, Switzerland	CareFusion Italy, 312 S.p.A. Unipersonale, Via Giacomo Matteotti 27/A, Villamarzana, Rovigo, 45030 Italy	ISO 13485: 2003 certificate number MD 71300 (BSI)	BSI (British Standards Institution), No. 0086	506414	Italy

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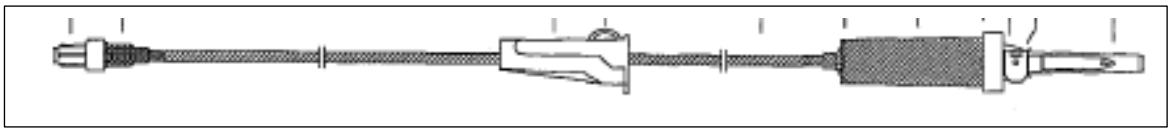
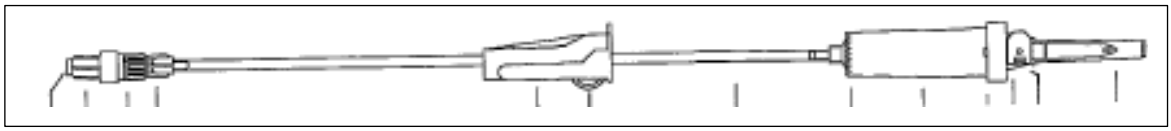
1.3 Material

Example of product configuration, product reference 03508411318



Example of product configuration, product reference 03508318429



COMPONENT	MATERIAL
INFUSION ADMINISTRATION SET, VENTED	
CAP FOR CLOSURE PIERCING DEVICE	PE
VENTED CLOSURE PIERCING DEVICE	ABS
HYDROPHOBIC AIR FILTER	HYDROPHOBIC PAPER
PLUG FOR HYDROPHOBIC AIR FILTER	PP
DRIP CHAMBER*	SB
FILTER 15 MIC.	PA 66
TUBING (MODEL 03508411318 THERMOPLASTIC ELASTOMER – PVC-FREE)	PVC (not with added DEHP)
ROLLER CLAMP (HOUSING AND WHEEL)	PS, ABS
FIX MALE LUER LOCK ADAPTER-OPAQUE (MODEL 03508411318)	ABS
PROTECTING CAP FOR FIX MALE LUER LOCK ADAPTER (MODEL 03508411318)	PE
ROTATING LUER LOCK ADAPTER (MODEL 03508318429)	ABS
HYDROPHOBIC CAP FOR LUER LOCK ADAPTER (MODEL 03508318429)	PE
HYDROPHOBIC FILTER (MODEL 03508318429)	ACRYLIC COPOL.

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PACKAGING	
UNIT PACK	PEEL PACK 100x220 mm made of FFS TOP WEB: 60gsm MEDICAL GRADE PAPER, FFS FILM: 80 g/m2 PP/PA/PE coextruded film
SHELF CONTAINER (INTERNAL PACKAGING)	POLYETHYLENE BAG
EXPORT CONTAINER (EXTERNAL PACKAGING)	CARTON

***) 20 drops milliliter**

Tube dimension and priming volume

PRODUCT REFERENCE	PRIMING VOLUME (ML)	TUBE INNER DIAMETER (MM)	TUBE OUTER DIAMETER (MM)
03508411318	16	3	4
03508318429	19	3	4

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 / DEHP	DEHP is not part of material formulation.
Latex	Natural rubber LATEX is not part of material formulation.
Bisphenol A	The products 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)	Polyvinyl chloride is not part of material formulation. Exception is model 03508318429, by which some components or parts of components are made of PVC, moreover not with added DEHP.

1.5 REACH information

BD maintains an active REACH compliance program and works closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern (“SVHC”) through regular communication and exchange.

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.

1.7 Sterilization

Sterilization Method: ***Ethylene Oxide Sterilization;*** followed standard EN ISO 11135-1 "Sterilization for Healthcare 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. All references are sterilized with EO.

ETO Product Residue Test Results Summary - Example product

Test	Method	Result	Unit
EO residual	UNI EN ISO 10993-7:2009/EC1:2010 simulated-use extraction	< 0,1	mg/device

Note:

Given example values are taken from tests on similar product to the products in this technical file (worst case scenario). More information related to specific product/batch is available on request.

1.8 Shelf life

Shelf life is 3 years for all product references in this technical data sheet, except 03508411318, for which it is 5 years. For storage and transportation condition pls. check the information on the packaging and labeling.
Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

1.9 Standards

BS EN 556-1: 2001/AC2006	Sterilisation of Medical Devices – Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 1041: 2008 + A1: 2013	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer of medical devices
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 8536-10: 2015	Infusion equipment for medical use. Part 10: Infusion accessories
BS EN ISO 10993-1: 2009	Biological evaluation of medical devices. Evaluation and testing

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BS EN ISO 10993-4: 2017	Biological evaluation of medical devices. Selections of tests for interactions with blood
BS EN ISO 10993-5: 2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
BS EN ISO 10993-7: 2008	Biological evaluation of medical devices. Ethylene oxide sterilization residuals
BS EN ISO 10993-10: 2013	Biological evaluation of medical devices. Tests for initiation and sensitization
BS EN ISO 10993-11: 2009	Biological evaluation of medical devices. Tests for systemic toxicity
BS EN ISO 11135: 2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11607-1: 2009/A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2: 2006/A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11717-1: 2006	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: Test of sterility performed in the definition, validation and maintenance of a sterilization process
BS EN ISO 13485: 2012	Quality systems – Medical devices – Particular requirements for the application of EN ISO 9001 (revision of EN 460001:1996) (identical to ISO 13485:1996)
14644-1: 2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness
14644-2: 2015	Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with 14644-1.
14644-5: 2004	Cleanrooms and associated controlled environments -- Part 5: Operations
BS EN ISO 14971: 2012	Medical Devices. Application of risk management to medical devices
BS EN ISO 15223-1: 2016	Medical devices. Symbols to be used with medical devices labels, labelling and information to be supplied
BS EN 15986: 2011	Symbol for use in the labelling in medical devices - Requirements for labelling of medical devices containing phthalates
BS EN ISO 80369-7: 2017	Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications
ISTA-1A - 2014 Edition	Packaged-Products 150 Lb (68 Kg) or less
ISTA-2A - 2012 Edition	Packaged-Products 150 Lb (68 Kg) or less

Note: Given standards are referring to the status at the moment of preparation of this document. More information or updates are available on request.

1.10 Classification

Class I Sterile, Rule 2, Infusion Administration Set for Gravity, in accordance with Council Directive 93/42/EEC, Annex IX, Rule 2

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1.11 GMDN code

GMDN code: 58977, (Basic intravenous administration set)
GMDN Description: A collection of sterile devices designed to conduct the fluids from an intravenous (IV) fluid container to a patient's venous system. It typically includes tubing, connectors, chambers, clamps, and needleless or injection ports. It is typically used for gravitational intravenous administration. This is a single-use device.

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 Other Information

- (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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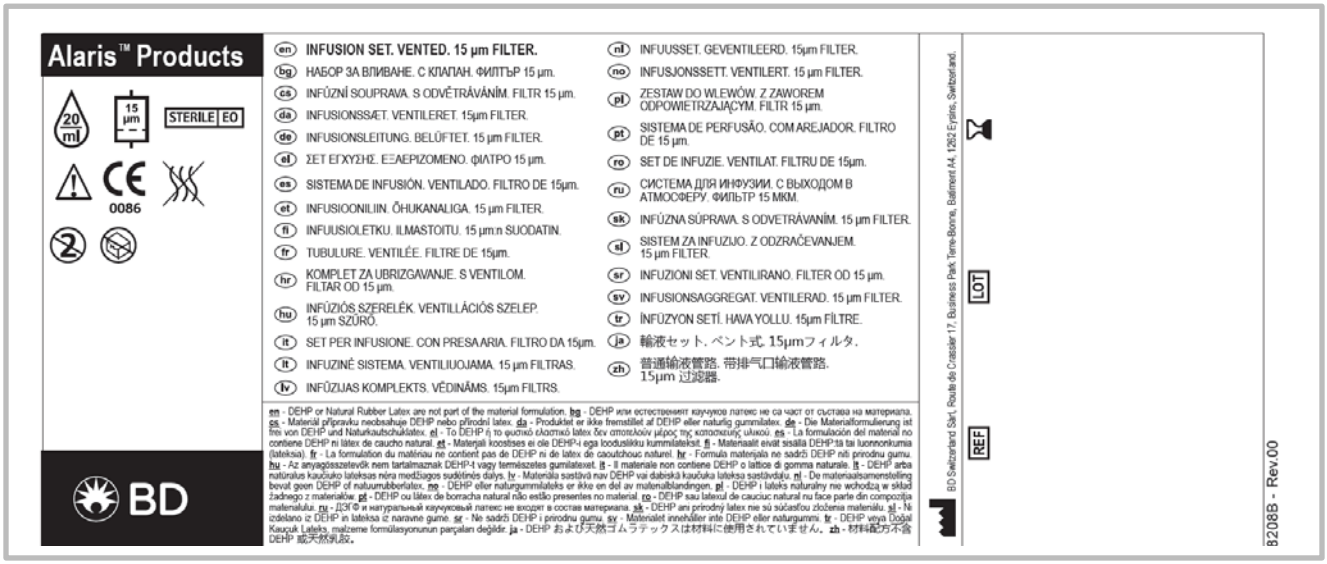
2. Packaging

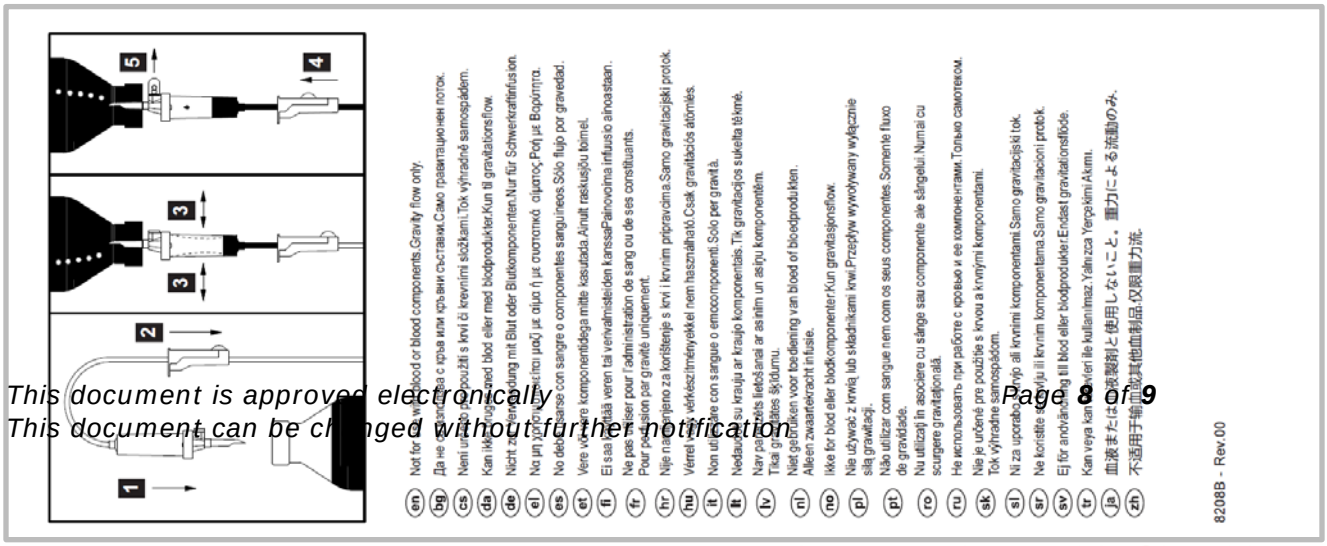
2.1 Example unit pack labeling

UNIT CONTAINER LABELLING PRINTED WITH 28 LANGUAGES:
ENGLISH, BULGARIAN, CZECH, CROATIAN, DANISH, GERMAN, GREEK, SPANISH, ESTONIAN, FINNISH, FRENCH, HUNGARIAN, ITALIAN, LITHUANIAN, LATVIAN, DUTCH, NORWEGIAN, POLISH, PORTUGUESE, ROMANIAN, RUSSIAN, SERBIAN, SLOVAK, SLOVENE, SWEDISH, TURKISH, JAPANESE, CHINESE

Example unit pack label, product reference 03508318429, first page



Example unit pack label, product reference 03508318429, second page



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2.2 Shipper label

Example product reference 03508318429

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