« Back to search results

BD Arterial Cannula

SKU/REF	682245
SKU/REF Name	BD Arterial Cannula

Specifications

Size	20G X 1.75IN
Gauge	20GA
Gauge Size (mm)	1.1
Length (inch)	1.75
Length (mm)	45
Flow (ml/min)	49
Quantity per Shelf Box	500
Quantity per Case	500
Sterilization method	Ethylene Oxide
Classification	IIa
Shelf Life	5 Years
Country Of Manufacture	Singapore
DEHP	DEHP Free
Latex	Latex Free
PVC	PVC Free

Please note, not all products, services or features of products and services may be available in your local area. Please check with your local BD representative.

CE
2797

Regulatory documents

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BD Medical
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford, Oxfordshire, OX4 4DQ

tel: +44 (0)1865 748844
fax: +44(0)1865 717313
www.bd.com

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TECHNICAL DATA SHEET No: Art Can

TECHNICAL DATA SHEET

BD Arterial Cannula with Flowswitch

REF	GAUGE	SIZE (MM)	ML/MIN
682245	20G	1.10 x 45	49

Product Photograph

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GENERAL INFORMATION

Intended Use

The Arterial Cannula is a sterile, non pyrogenic, disposable catheter designed to allow peripheral access to the human circulatory system. It is indicated for patients requiring continuous direct blood pressure monitoring and arterial blood gas sampling.

Legal Manufacturer - Name and Address

Plant Regulatory Affairs Manager – Batsy Lo
European Regulatory Affairs and Compliance Manager – Jeremy Allen

Production Site - Name and Address

Becton Dickinson Critical care Systems Pte Ltd.
198 Yishun Ave 7
Singapore 768926
Singapore

EU Authorised Representative - Name and Address

Becton Dickinson Distribution Centre NV
Laagstraat 57
9140, Temse
Belgium

Certification

Certificate	Notified Body
CE Certifícate Medical Devices Directive 93/42/EEC - Annex II Certificate No. CE01982	British Standards Institution, Inc. Medical Devices BSI Product Service Maylands Avenue Hemel Hempstead HP2 4SQ United Kingdom **Notified Body Number: 0086**
ISO 13485:2003	British Standards Institution, Inc. Medical Devices BSI Product Service Maylands Avenue Hemel Hempstead HP2 4SQ United Kingdom **Notified Body Number: 0086**

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Classification and GMDN Data

Device Class

The product is intended for short term surgically invasive access to the human circulatory system. The product is classified as a Class IIa medical device in accordance with Annex IX of the European Medical Devices Directive 93/42/EEC under rule 7.

GMDN

34893 – Cannula, Arterial

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SPECIFICATION INFORMATION

Approved Materials of Construction

Component	Material
Catheter Bush	Polycarbonate
Flowswitch Button Red	Polyphenylene Oxide
Flowswitch Housing	Polypropylene
Flow Control Plug	Polypropylene
Guide Bush	Polycarbonate
Needle Grip	Polypropylene
Protection Tube	Polyethylene
Catheter Tube	Telfon
Needle	Stainless Steel
Needle Lubricant	Medical Grade Silicone

Labelling Languages

Item	Language	ISO 639-1 Code
1	Bulgarian	bg
2	Croatian	hr
3	Czech	cs
4	Danish	da
5	Dutch	nl
6	English	en
7	Estonian	et
8	Finnish	fi
9	French	fr
10	German	de
11	Greek	el
12	Hungarian	hu
13	Italian	it
14	Italian	lt
15	Latvian	lv
16	Norwegian	no
17	Polish	pl
18	Portuguese	pt
19	Romanian	ro
20	Russian	ru
21	Slovakian	sk
22	Slovenian	sl
23	Spanish	es
24	Swedish	sv
25	Turkish	tr

Sterilisation Method/Shelf Life

Ethylene Oxide

5 years shelf life post sterilisation

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Standards Compliance

Standard	Title
ISO 594-1	Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements
ISO 594-2	Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
ISO 10555-1	Sterile Single-use intravascular catheters – Part 1 – General Requirements
ISO 10555-5	Sterile Single-use intravascular catheters – Part 5 – over-the-needle peripheral catheters

Reference to QDMS Documents

Document Title	QDMS Reference
Technical File	090002-000-019
Clinical Evaluation	RTF63
Risk Management Summary	090004-001-019
Specification	094010-000-072

Packaging Characteristics

Unit

Quantity	1

Shelf

Quantity	25

Case

Quantity	200

Materials of Concern

Material	Present (No/Yes)
DEHP/Phthalate	No
Latex	No
Substances of animal origin BSE/TSE	No
PVC	No

Revision Number

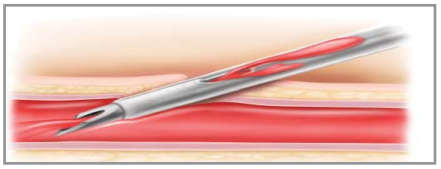
Revision 1

Date

28th February 2012

BD Insyte-A™ Arterial Catheters

- Barrel Seal
  – the depressing of the plunger minimises back flow of blood, reducing the risk of blood exposure
- Plunger Head
  – when the plunger head is in line with the marker on the barrel, the guidewire is in line with the needle tip
- Large Flashback Chamber
  – the large transparent flashback chamber enables confirmation of vessel puncture
- Round Tip Guidewire
  – the round tipped guidewire aids smooth securing of the blood vessel
- Sterilization method: ethylene oxide
- Sterile, single use
- CE marked
- Manufactured in BD Vialon™, a unique polyurethane, radiopaque biocompatible catheter material (please see page 40 for further information)



BD Instaflash™ Technology.
Designed to reduce hit-and-miss insertion.

Gauge Size	Outer Diameter (mm)	Length (mm)	Color Code	Shelf Box / Shipping Case	Reference Number
BD Insyte-A™ Arterial Catheters					
22 G	0,9	38	blue	20 / 80	382802
20 G	1,1	38	pink	20 / 80	382805

1 pd

BD™ Arterial Cannula with BD Floswitch™ One-Way-Stopcock

- Catheter designed for insertion into peripheral arteries, for the determination of blood gas estimations or monitoring blood pressure
- 'BD Venflon™-like' insertion characteristics
- Wings to facilitate fixation
- Class IIa according to European Medical Devices Directive 93/42/EEC
- Sterilization method: ethylene oxide
- Sterile, single use
- CE marked
- The BD Floswitch™ On/Off device prevents back-flow and reduces the risk of air emboli and potential contamination of hospital staff by exposure to blood

Gauge Size	Outer Diameter (mm)	Length (mm)	Color Code	Shelf Box / Shipping Case	Reference Number
BD™ Arterial Cannula with BD™ Floswitch™ One-Way-Stopcock					
20 G	1,1	45	red	25 / 500	682245

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01738**

Issued To: **Becton Dickinson Infusion Therapy Systems Inc.**
9450 South State Street
Sandy
Utah
84070
USA

In respect of:

The design, development and manufacture of sterile peripheral vascular and subcutaneous access catheters, accessory devices and infusion sets.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-10-03** Date: **2021-05-10** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01738

Issued To:

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
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USA

Number	Device Name	Intended purpose as per IFU
Class IIa		
MD 0102	BD Angiocath™ IV Catheter	---
MD 0102	BD Angiocath™ IV Catheter for Special Placement	---
MD 0102	BD Angiocath Plus™ I.V. Catheter	---
MD 0102	BD Arterial Cannula	---
MD 0102	BD Cathena™ Safety IV Catheter	---
MD 0102	BD Cathena™ Safety IV Catheter with Wings	---
MD 0102	BD Insyte™ IV Catheter	---
MD 0102	BD Insyte-N™ IV Catheter	---
MD 0102	BD Insyte-N™ IV Catheter with Wings	---
MD 0102	BD Insyte-W™ IV Catheter with Wings	---
MD 0102	BD Insyte™ Autoguard™ Shielded IV Catheter	---
MD 0102	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	---
MD 0102	BD Insyte-N™ Autoguard™ Shielded IV Catheter	---
MD 0102	BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter	---

First Issued: **1997-10-03** Date: **2021-05-10** Expiry Date: **2024-05-26**

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Supplementary Information to CE 01738

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Number	Device Name	Intended purpose as per IFU
MD 0102	BD Insyte™ Autoguard™ BC Shielded IV Catheter	---
MD 0102	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter	---
MD 0102	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	---
MD 0102	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	---
MD 0102	BD Neoflon™ Pro Safety IV Catheter	---
MD 0102	BD Neoflon™ Pro Safety IV Catheter with Wings	---
MD 0102	BD Nexiva™ Closed IV Catheter System	---
MD 0102	BD Nexiva™ Closed IV Catheter System – Single Port	---
MD 0102	BD Nexiva™ Closed IV Catheter System – Dual Port	---
MD 0102	BD Nexiva™ Diffusics™ Closed IV Catheter System	---
MD 0102	BD Saf-T-Intima™ Safety System with Removable PRN	---
MD 0102	BD Saf-T-Intima™ Safety System with Y Adapter	---
MD 0102	BD Introsyte™ Precision Introducer	---
MD 0102	BD Introsyte-N™ Precision Introducer	---
MD 0102	BD Introsyte™ Autoguard™ Shielded Introducer	---

First Issued: **1997-10-03** Date: **2021-05-10** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01738

Issued To:

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
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Number	Device Name	Intended purpose as per IFU
MD 0102	BD Introsyte-N™ Autoguard™ Shielded Introducer	---
MD 0102	BD Q-Syte™ Luer Access Split Septum	---
MD 0102	BD Q-Syte™ Vial Access Adapter	---
MD 0102	BD Q-Syte™ Extension Sets	---

First Issued: **1997-10-03** Date: **2021-05-10** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01738**
Date:	**2021-05-10**
Issued To:	**Becton Dickinson Infusion Therapy Systems Inc.** **9450 South State Street** **Sandy** **Utah** **84070** **USA**

Subcontractor:	**Service(s) supplied**
Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium	**EU Representative**
Becton Dickinson Industrias Cirurgicas Ltda Rua Cyro Correia Pereira 550 Curitiba 81170-230 Brazil	**ETO Sterilization**
Becton Dickinson Industrias Cirurgicas Ltda Av. Pres. Juscelino Kubitscheck, 273 Francisco Bernardino Juiz de Fora MG 36081-000 Brazil	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Date:	**2021-05-10**
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Subcontractor:	**Service(s) supplied**
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Mexico	**Manufacture**
Becton Dickinson Medical (S) Pte. Ltd. 30 Tuas Avenue 2 639461 Singapore	**ETO Sterilization** **Manufacture**
Becton Dickinson Medical Devices Co., Ltd. Suzhou No. 5 Baiyu Road, Suzhou Industrial Park Jiangsu P.R. China	**ETO Sterilization** **Manufacture**
Becton Dickinson Medical Products Research & Development 30 Tuas Avenue 2 639461 Singapore	**Design**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Becton Dickinson San Diego 10020 Pacific Mesa Blvd. San Diego California 92121 USA	**Design**
Innovative Medical Manufacturing Company No. 107, LN. 181 Sec. 1, Yongzhen Rd. Zhunan Township Miaoli County 35057 Taiwan (R.O.C)	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351 Parque Industrial El Florido Seccion Vistas 1 Tijuana Baja California CP22244 Mexico	**Manufacture**
Sterile Services (Singapore) Pte. Ltd. No. 47A Jalan Buroh Module 6, CWT Distripark 619492 Singapore	**ETO Sterilization**
Sterile Services (Singapore) Pte. Ltd. No. 47 Jalan Buroh, Unit #01-01, Singapore 619491	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01738**

Date: **2021-05-10**

Issued To: **Becton Dickinson Infusion Therapy Systems Inc.**
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Date	Reference Number	Action
03 October 1997		First Issue.
01 November 2001		Obturators removed from the scope. BD (Tuas Avenue – Singapore) added to the list of subcontractors. Novalon®, Autoguard™ Pro and Angiocath® Autoguard™ added to list A.
25 July 2002		TFX Medical (Ireland), BD (Curitiba – Brazil) and BD (Juiz de Fora – Brazil) added to list of subcontractors.
20 December 2002		'Development' added to the scope. BD (Jiangsu – PR of China) added and TFX Medical (Ireland) removed from the list of subcontractors.
17 January 2003		Introsyte™ Autoguard, MST Accessory Kits, Saf-T PRN added and E-Z set; IV Start Pak® Kits (dry) and Minicath® deleted from product listing. ETO added as an activity for BD (Jiangsu – PR of China).
16 February 2005		Change of address of BD (Sonora – Mexico) and change of name of IBA/Griffith to Sterigenics, Inc. Product Saf-T PRN changed name to Q-Syte™. Delete Angioset®, add OneCath™ Midline, L-Cath Midline and BD Splittable Needle.
05 October 2005		Sterile Services (Singapore) added to the list of subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
22 September 2006		Sterigenics, Salt Lake, Utah added as sterilization to the list of subcontractors.
25 July 2007		Addition of the word 'sterile' to scope. Addition of Becton Dickinson Infusion Therapy Systems Inc. as a subcontractor to reflect in-house ability to carry out ethylene dioxide sterilization.
03 October 2007		Certificate renewal.
28 April 2008	7187006	Product listing modified to remove Insyte-N™, Saf T E-Z Set™, OneCath™ Midline and Autoguard™ Pro. BD PRN Adapter added and BD prefix added to all products other than Accessories.
03 September 2009	7438548	Product listing updated to add BD Angiocath Plus™
26 September 2012	7878324	Renewal with scope extension to include 'and subcutaneous'. Minor amendments to the list of subcontractors and addition of the EU Representative.
10 April 2013	7947780	Product listing updated to add 'BD Arterial Cannula'.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01738**

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Date	Reference Number	Action
17 July 2014	8184052	Addition of Innovative Medical Manufacturing Company and STERIS Isomedix Services (Temecula, CA, USA) to the list of significant subcontractors. Minor administrative changes to the list of significant subcontractors.
18 September 2015	8411832	Removal of BD Posiflow devices, removal of Steris (Temecula) from the list of subcontractors.
07 April 2017	8693872	Addition of CareFusion (Yorba Linda, CA, USA) and Sistemas Medicos Alaris SA de C.V. (Tijuana, Mexico) to the listed subcontractors. Minor administrative changes to the list of subcontractors.
03 October 2017	8794620	Certificate Renewal. Addition of subcontractor Carefusion 303, Inc. (10020 Pacific Mesa Boulevard, San Diego, California, 92121 USA) as Design subcontractor for BD Q-Syte, BD PRN Adapter, BD I.V. Loop and J Loop. Addition of BD Cathena to the product listing.
03 May 2018	8919063	Addition of the BD Neoflon™ Pro Safety IV Catheters to the product list.
11 March 2019	9706521	Addition of manufacturing subcontractor Becton Dickinson de Mexico, S.A. de C.V. for the manufacture of components for the BD Saf-T-Intima product.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-05-10**

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Date	Reference Number	Action
13 March 2019	7780583	Traceable to NB 0086.
06 September 2019	9773255	Addition of design subcontractor Becton Dickinson Medical Products for BD Arterial Cannula. Removal of subcontractor CareFusion (Yorba Linda, CA, USA).
13 July 2020	9755045	Certificate Renewal. Reduction of scope to remove 'IV Start Kits'. Removal of BD Intima, Angiocath Autoguard and I.V. Loop. General update to product supplementary information table. Removal of subcontractor 'Becton Dickinson de Mexico, S.A. de C.V. (Cuautitlan Izcalli)', 'Becton Dickinson Infusion Therapy Systems Inc (Sandy)', 'Sterigenics US, LLC (Santa Teresa)', 'Sterigenics US, LLC (Salt Lake City)' & 'STERIS Isomedix Services Inc (Sandy)'. Update to subcontrator's name (CareFusion 303, Inc to Becton Dickinson San Diego) in line with vendor's ISO 13485 certificate. Update to subcontractors' addresses (Becton Dickinson Industrias Cirurgicas Ltda (Curitiba), Becton Dickinson Industrias Cirurgicas Ltda (Juiz de Fora MG), Innovative Medical Manufacturing Company (Taiwan) & Sterile Services (Singapore) Pte. Ltd (Singapore) in line with vendor's ISO 13485 certificates.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01738**

Date: **2021-05-10**

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Date	Reference Number	Action
23 September 2020	3290239	Removal of subcontractor Becton Dickinson Medical Devices Co., Ltd (Suzhou). Update to products table in supplementary information section to remove BD PRN Adapter and BD J-Loop.
09 April 2021	3404939	Addition of subcontractor Becton Dickinson Medical Devices Co., Ltd. Suzhou (China).
Current	3427810	Addition of subcontractor Sterile Services (Singapore) Pte. Ltd. (Singapore).