

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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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 01738

Issued To:

**Becton Dickinson Infusion
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9450 South State Street
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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	---

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Page 2 of 4

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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	---

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Page 3 of 4

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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	---

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Page 4 of 4

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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:

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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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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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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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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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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.

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Page 1 of 5

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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'.

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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.

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Page 3 of 5

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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 subcontractor'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.

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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).