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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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
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

Issued To:

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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:

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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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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 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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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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.**
9450 South State Street
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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: **2021-05-10**
Issued To: **Becton Dickinson Infusion Therapy Systems Inc.**
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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**

Date: **2021-05-10**

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

Certificate No: **CE 01738**

Date: **2021-05-10**

Issued To: **Becton Dickinson Infusion Therapy Systems Inc.**
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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**

Issued To: **Becton Dickinson Infusion Therapy Systems Inc.**
9450 South State Street
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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).

BD Switzerland Sàrl

Route de Crassier 17
Business Park Terre-Bonne
Bâtiment A4
1262 Eysins
Switzerland

July 30 2024

Notified Body Confirmation Letter

Reference: EU2023-607/705068 rev.3

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BD Switzerland Sàrl

Route de Crassier 17
Business Park Terre-Bonne
Bâtiment A4
1262 Eysins
Switzerland

SRN Number: CH-MF-000026539

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Infusion Administration Set for Gravity	Class I device placed on the market in sterile condition	N/A	CE 506414; NB 2797
VP Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
Texium Closed Male Luer	Class IIa	N/A	CE 502238; NB 2797
Pressure Extension Tubing	Class IIa	N/A	CE 502238; NB 2797
Manifolds, Stopcock, Valve	Class IIa	N/A	CE 502238; NB 2797
Gemini Administration Sets	Class IIa	N/A	CE 502238; NB 2797
Access Device	Class IIa	N/A	CE 502238; NB 2797
SmartSite Needle-free Valve	Class IIa	N/A	CE 502238; NB 2797
Gravity IV Sets, Extension Sets & Components	Class IIa	N/A	CE 502238; NB 2797
GW Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
Extension Sets	Class IIa	N/A	CE 502238; NB 2797
GP Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
MaxPlus™ Needleless Connectors	Class IIa	N/A	CE 502238; NB 2797
MaxPlus Extension Sets	Class IIa	N/A	CE 502238; NB 2797
Texium Needle-Free Syringe	Class IIa	N/A	CE 502238; NB 2797
MaxZero™ Needleless Connector	Class IIa	N/A	CE 502238; NB 2797
MaxZero™ Extension Sets	Class IIa	N/A	CE 502238; NB 2797
Alaris™ GP Volumetric Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ VP Volumetric pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ CC Syringe Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Alaris™ PK Syringe Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ Gateway Workstation	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ Communication Engine	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ Editors	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
BD Q-Syte Devices	Class IIa	N/A	CE 01738; NB 2797
BD Q-Syte™ Vial Access Adapter	Class I device placed on the market in sterile condition	N/A	CE 01738; NB 2797
BD Vial/Bag Access Devices	Class I device placed on the market in sterile condition	N/A	CE 506414; NB 2797
Infusion Administration Set for Gravity	Class IIa	N/A	CE 502238; NB 2797
Alaris GP Volumetric Pump Sets	Class IIa	Alaris SE Infusion Sets	CE 502238; NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/11/05	Initial issue
2024/29/02	Addition of BD Q-Syte Devices, BD Q-Syte™ Vial Access Adapter, BD Vial/Bag Access Devices
2024/05/08	Addition of Infusion Administration Set for Gravity
2024/07/30	Addition of Alaris GP Volumetric Pump Sets