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By Royal Charter

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	---

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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**

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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 Certificate History

Certificate No: **CE 01738**

Date: **2021-05-10**

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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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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'.

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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.

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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.

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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).
10 May 2021	3427810	Addition of subcontractor Sterile Services (Singapore) Pte. Ltd. (Singapore).
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
03 December 2024	30286903	Removal of subcontractor for sterilization of BD Arterial Cannula, BD Angiocath Plus, and BD Insyte devices. The Class IIa BD Introsyte™ Introsyte-N™, Introsyte™ Autoguard™, and Introsyte-N™ Autoguard™ Introducers are removed from the device table.

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Inspiring trust for a more resilient world.

03 December 2024

Becton Dickinson Infusion
Therapy Systems Inc.
9450 South State Street
Sandy
Utah
84070
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 01738	93/42/EEC Annex II excluding Section 4	30286903	Removal of subcontractor Sterile Services (Singapore) Pte Ltd for sterilization of BD Arterial Cannula, BD Angiocath Plus, and BD Insyte devices. The Class IIa BD Introsyte™ Introsyte-N™, Introsyte™ Autoguard™, and Introsyte-N™ Autoguard™ Introducers are removed from the device table.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com bsigroup.nl