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, IV start kits, 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1997-10-03** Date: **2017-10-03** Expiry Date: **2022-10-02**

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Supplementary Information to CE 01738

Issued To:

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy
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Product

The following product families are listed in conjunction with EC Certificate CE 01738:

BD Angiocath™	BD Introsyte™ Introducers
BD Angiocath™ Autoguard™	BD Nexiva™
BD I.V. Loop and J Loop	BD PRN Adapter
BD Insyte™	BD Q-Syte™
BD Insyte™ Autoguard™	BD Saf-T-Intima™
BD Intima™	BD Angiocath Plus™
BD Introsyte™ Autoguard™	BD Cathena™
BD Arterial Cannula	

First Issued: **1997-10-03** Date: **2017-10-03** Expiry Date: **2022-10-02**

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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:

Certificate No:	**CE 01738**
Date:	**2017-10-03**
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Subcontractor:	**Service(s) supplied**
STERIS Isomedix Services Inc. 9120 South 150 East Sandy Utah 84070 USA	**ETO Sterilization**
Becton Dickinson Industrias Cirurgicas Ltda R. Cyro Correia Pereira, 550 Cidade Industrial Curitiba Parana Brasil	**ETO Sterilization**
CareFusion 303, Inc. 10020 Pacific Mesa Boulevard San Diego California 92121 USA	**Design**

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Subcontractor:	**Service(s) supplied**
Becton Dickinson Medical (S) Pte. Ltd. 30 Tuas Avenue 2 639461 Singapore	**ETO Sterilization** **Manufacture**
Becton Dickinson Industrias Cirurgicas Ltda Avenida Presidente Juscelino Kubitschek, 273 Francisco Bernardino Juiz de Fora-MG 36081-000 Brasil	**Manufacture**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Becton Dickinson Medical Devices Co., Ltd. (Suzhou) No. 5 Baiyu Road Suzhou Industrial Park Jiangsu China	**ETO Sterilization** **Manufacture**
Sterile Services (Singapore) Pte. Ltd. No. 47A Jalan Buroh, Module 6, CWT Distripark 619491 Singapore	**ETO Sterilization**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy Utah 84070 USA	**ETO Sterilization** **Manufacture**
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Mexico	**Manufacture**
Innovative Medical Manufacturing Company No. 107, Lane 181 Sec. 1 Yong Jane Rd. Chunan, Miaoli 350 Taiwan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium	**EU Representative**
CareFusion 22745 Savi Ranch Parkway Yorba Linda California 92887 USA	**Design**
Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351 Parque Industrial El Florido Seccion Vistas 1 Tijuana Baja California CP22244 Mexico	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01738**

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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.
22 September 2006		Sterigenics, Salt Lake, Utah added as sterilization to the list of subcontractors

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Date	Reference Number	Action
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'.
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.

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Date	Reference Number	Action
Current	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.