bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 597884**

Issued To: **Becton Dickinson**
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden

In respect of:

The design, development and manufacture of Sterile Intravenous Catheters and Fluid Administration Devices.

Those aspects of Annex II concerned with securing and maintaining sterile conditions of IV Dressings.

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: **2013-05-07** Date: **2021-05-12** Expiry Date: **2024-01-08**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 597884

Issued To:

Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden

Device code	Device name	Intended purpose per IFU
Class IIa		
MD0102	BD Venflon™ I.V. Cannula	---
MD0102	BD Venflon™ I I.V. Cannula	---
MD0102	BD Venflon™ Pro I.V. Cannula	---
MD0102	BD Venflon™ Pro I.V. Cannula with Instaflash™ Needle Technology	---
MD0102	BD Venflon™ Pro Safety I.V. Cannula	---
MD0102	BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology	---
MD0102	BD Connecta™ Stopcock with OFF directed tap without Extension Tube	---
MD0102	BD Connecta™ Stopcock without Extension Tube	---
MD0102	BD Connecta™ Stopcock with Extension Tube	---
MD0102	BD Connecta™ Stopcock with Low Volume Extension Tube	---

First Issued: **2013-05-07** Date: **2021-05-12** Expiry Date: **2024-01-08**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 597884

Issued To:

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Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
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Device code	Device name	Intended purpose per IFU
Class IIa		
MD0102	BD Connecta™ Stopcock with Extension Tube and Injection Valve	---
MD0102	BD Connecta™ Stopcock with BD Q-Syte™ Luer Access Split-Septum	---
MD0102	BD Plug Luer-Lok™	---
MD0102	BD™ IV Sets and Accessories	---
MD0102	BD Venflon™ Obturators	---
MD0102	BD Insyte™ Obturators	---
MD0102	BD Neoflon™ I.V. Cannula	---
MD0102	BD Neoflon™ Pro I.V. Cannula	---
Class Is		
MD0301	BD Veca-C™ I.V. Dressing	---
MD0301	BD Vecafix™ I.V. Dressing	---

First Issued: **2013-05-07** Date: **2021-05-12** Expiry Date: **2024-01-08**

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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 597884**
Date:	**2021-05-12**
Issued To:	**Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden**

Subcontractor:	**Service(s) supplied**
Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore	**ETO Sterilization Manufacture Packaging**
Becton Dickinson India Pvt. Ltd. Plot No. 1, Sector 3, IMT Bawal, District Rewari Haryana - 123501 India	**ETO Sterilization Manufacture Packaging**
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy Utah 84070 USA	**ETO Sterilization**

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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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Date:	**2021-05-12**
Issued To:	**Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden**

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** **Packaging**
Becton Dickinson Medical Products Research & Development 30 Tuas Avenue 2 639461 Singapore	**Design**
CareFusion 303, Inc. 10020 Pacific Mesa Blvd. San Diego California 92121 USA	**Design**

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EC Certificate - Full Quality Assurance System

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

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Issued To:	**Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden**

Subcontractor:	**Service(s) supplied**
Electron Beam SDN. BHD. Lot 7 Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (FASA 2) 42920 Port Klang Selangor Malaysia	**Radiation (E Beam Sterilization)**
Raja Ramanna Centre for Advanced Technology (RRCAT), Indore Agricultural Radiation Processing Facility (ARPF) Devi Ahilyabai Holkar Fruit and Vegetable Mandi Complex Indore – 452 013 Madhya Pradesh India	**Radiation (E Beam Sterilization)**
Sterigenics Denmark A/S Aa Louis-Hansens Alle 11 Espergaerde, Region Sjaelland DK-3060 Denmark	**Radiation (E Beam Sterilization)**

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EC Certificate - Full Quality Assurance System

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

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Subcontractor:	**Service(s) supplied**
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	**ETO Sterilization**
Sterigenics US LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Sterigenics US LLC 7695 Formula Place San Diego CA 92121 USA	**Radiation (E Beam Sterilization)**

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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 597884**
Date:	**2021-05-12**
Issued To:	**Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden**

Subcontractor:	**Service(s) supplied**
Sterile Services (Singapore) Pte. Ltd. No.47A Jalan Buroh Module 6 CWT Distripark Singapore 619492	**ETO Sterilization**
Sterile Services (Singapore) Pte. Ltd. No. 47 Jalan Buroh, Unit #01-01, Singapore 619491	**ETO Sterilization**
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego, California 92126 USA	**Radiation (E Beam Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 597884**

Date: **2021-05-12**

Issued To: **Becton Dickinson**
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden

Date	Reference Number	Action
07 May 2013	7974112	First Issue. Mirror of CE 01141.
09 January 2014	8094008	Addition of Synergy Health to list of significant subcontractors and minor changes to address. Certificate renewal.
06 June 2016	8543101	Addition of Sterigenics S.de R.L. de C.V to list of significant subcontractors.
30 August 2016	8588613	'Becton Dickinson India Pvt. Ltd.' correction of the subcontractor address.
22 November 2016	8314801	Extension of scope to include class I sterile IV dressings.
19 January 2018	8886572	Addition of Design Locations and New Design Subcontractors: Carefusion 303, Becton Dickinson Infusion Therapy System Inc. and Becton Dickinson Medical Products Research & Development. Addition of Sterilization Subcontractor SterilMilano S.r.l and sterilization service from existing subcontractor Becton Dickinson Medical (S) Pte Ltd. Addition of Manufacture subcontractor CareFusion BH. Name change to STERIS Applied Sterilization Technologies (previously Synergy Health).

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 597884**

Date: **2021-05-12**

Issued To: **Becton Dickinson**
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden

Date	Reference Number	Action
14 December 2018	9652480	Certificate Renewal. Removal of obsolete subcontractors: Ebster s.r.o (ETO sterilization) Flextronics Romania S.R.L (Manufacture & Packaging) Sterigenics, Denmark (E Beam Sterilization) Sterigenics S. de R.L. de CV (ETO sterilization) Subcontractor details updated for the following subcontractors: Sterigenics Germany Sterile Services (Singapore) Pte Ltd. SterilMilano STERIS Applied Sterilization Technologies (Synergy Health AST, LLC)
22 February 2019	8251034	Traceable to NB 0086.
05 April 2021	3409337	Removal of subcontractor SterilMilano S.r.l (Reggiolo, Italy).
12 May 2021	3422423	Addition of subcontractor Sterigenics Denmark A/S (Denmark) and Sterile Services (Singapore) Pte. Ltd. (Singapore 619491). Addition of product table. Correction to subcontractor name and address.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 597884**

Date: **2021-05-12**

Issued To: **Becton Dickinson**
Infusion Therapy AB
Florettgatan 29C
PO Box 631
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Sweden

Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
16 August 2021	3495557	Addition of critical subcontractor i.e., Synergy Health Ede BV (Address: Faunalaan 38, Venlo, 5928 RZ, The Netherlands).
01 October 2021	3498904	The Class IIa BD IV Sets and Accessories, BD Venflon Obturators and BD Insyte Obturators are removed from the device table. Removal of subcontractors Carefusion BH 335 d.o.o. Cazin and Synergy Health Ede BV. Removal of 'design', manufacture' and 'packaging' services from subcontractor Becton Dickinson Infusion Therapy Systems (Sandy, UT).
23 February 2022	3622905	The Class IIa BD Venflon Pro I.V. Cannula with Instaflash Needle Technology devices are removed from the device table.
28 September 2022	3701522	Addition of subcontractor Raja Ramanna Centre for Advanced Technology (India). The class IIa BD Neoflon I.V. Cannula devices are removed from the device table.

Inspiring trust for a more resilient world.

28 September 2022

Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden

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 597884	93/42/EEC Annex II excluding Section 4	3701522	Addition of subcontractor Raja Ramanna Centre for Advanced Technology (India). The class IIa BD Neoflon I.V. Cannula devices 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

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