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:

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 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

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 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

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**
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)**
Sterigenics Denmark A/S Aa Louis-Hansens Alle 11 Espergaerde, Region Sjaelland DK-3060 Denmark	**Radiation (E Beam Sterilization)**
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	**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

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**
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)**
Sterile Services (Singapore) Pte. Ltd. No. 47 Jalan Buroh, Unit #01-01, Singapore 619491	**ETO Sterilization**

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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

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**
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.

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
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.

Inspiring trust for a more resilient world.

23 February 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	3622905	The Class IIa BD Venflon Pro I.V. Cannula with Instaflash Needle Technology 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,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
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John M. Keynesplein 9
1066 EP Amsterdam
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Becton Dickinson Infusion Therapy AB

Florettgatan 29C

PO Box 631

SE-251 06 Helsingborg

Sweden

September 21, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/693660

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:

Becton Dickinson Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden
SRN Number (if available): SE-MF-000014597

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.,

Luis Martinez

BSI Scheme Manager

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
BD Venflon Pro™ I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ I I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology	Class IIa	N/A	CE 597884; NB 2797
BD Venflon Pro™ Safety I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Neoflon™ Pro I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with OFF directed tap without Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock without Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Low volume Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Extension Tube and Injection valve	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with BD Q-Syte™ Luer Access Split-Septum	Class IIa	N/A	CE 597884; NB 2797
BD Plug Luer-Lok™	Class IIa	N/A	CE 597884; 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
2023/09/21	Initial issue