

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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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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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**

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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	---

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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:

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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
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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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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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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 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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 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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Certificate History

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Date: **2021-05-12**
Issued To: **Becton Dickinson
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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).

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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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Infusion Therapy AB
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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.

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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

Certyfikat WE – System pełnego zapewnienia jakości

Dyrektywa 93/42/EWG w sprawie wyrobów medycznych, Załącznik II, z wyłączeniem sekcji 4

Nr certyfikatu: CE 597884

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

W związku z:

Projektowaniem, rozwojem i produkcją sterylnych cewników dożylnych oraz wyrobów do podawania płynów.

Aspekty Załącznika II dotyczące zabezpieczenia i zachowania sterylnych warunków opatrunków mocujących do cewników dożylnych.

W oparciu o przeprowadzone przez nas badanie systemu zapewnienia jakości zgodnie z wymogami Dyrektywy Rady 93/42/EWG, Załącznik II, z wyłączeniem Sekcji 4. System zapewnienia jakości spełnia wymagania dyrektywy. W celu wprowadzenia na rynek wyrobów klasy III wymagany jest certyfikat uwzględniający Załącznik II Sekcja 4.

W imieniu na rzecz BSI, jednostki notyfikowanej dla powyższej dyrektywy (numer jednostki notyfikowanej 0086)

Podpis nieczytelny

Stewart Brain, Dyrektor Działu
Zgodności i Ryzyka – wyroby medyczne

Data pierwszego wydania 07.05.2013 Data: 14.12.2018

Data ważności: 08.01.2024

Certyfikat zachowuje ważność pod warunkiem utrzymania systemu jakości zgodnie z wymaganiami dyrektywy, co potwierdzono poprzez działania nadzorcze jednostki notyfikowanej. Zezwolenie nie obejmuje produktów zaprojektowanych i/lub produkowanych przez stronę trzecią w imieniu firmy wymienionej w certyfikacie, o ile nie zostanie to ustalone z BSI.
Certyfikat wydano w formie elektronicznej i podlega on warunkom umowy.

Lista istotnych dostawców

Uznanych za dostawców usług związanych z wyrobami objętymi:

Nr certyfikatu: CE 597884

Data: 14 grudnia 2018

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Podwykonawca	Świadczone usługi
Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapur	Sterylizacja ETO Produkcja Pakowanie
Becton Dickinson India PVT. Ltd. Plot No 1, Sector 2 IMT Bawal, District Rewari Haryana – 123501 Indie	Sterylizacja ETO Produkcja Pakowanie
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy Utah 84070 USA	Projekt Sterylizacja ETO Produkcja Pakowanie

Lista istotnych dostawców

Uznanych za dostawców usług związanych z wyrobami objętymi:

Nr certyfikatu: CE 597884

Data: 14 grudnia 2018

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Podwykonawca	Świadczone usługi
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Meksyk	Produkcja Pakowanie
Becton Dickinson MedicalProducts Research & Development 30 Tuas Avenue 2 639461 Singapur	Projekt
Carefusion 303 10020 Pacific Mesa Blvd. San Diego California 92121 USA	Projekt

Lista istotnych dostawców

Uznanych za dostawców usług związanych z wyrobami objętymi:

Nr certyfikatu: CE 597884

Data: 14 grudnia 2018

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Podwykonawca	Świadczone usługi
CareFusion BH 335 d.o.o. Cazin Mihaljevac bb Cazin 77720 Bośnia i Hercegowina	Produkcja Pakowanie
Electron Beam SDN. BHD Lot 7 Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (FASA 2) 42920 Port Klang Selangor Malezja	Sterylizacja z wykorzystaniem wiązki elektronów
Sterigenics Gemrany GmbH Kasteler Strasse Wiesbaden 65203 Niemcy	Sterylizacja ETO

Lista istotnych dostawców

Uznanych za dostawców usług związanych z wyrobami objętymi:

Nr certyfikatu: CE 597884

Data: 14 grudnia 2018

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Podwykonawca	Świadczone usługi
Sterigenic US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	Sterylizacja ETO
Sterigenic US. LLC RSI Leasing, Inc. 7695 Formula Place San Diego California 92121 USA	Sterylizacja z wykorzystaniem wiązki elektronów
Sterile Service (Singapore) Pte. Ltd. No. 47A Jalan Buroh Module 6 CWT Distripark 619491 Singapur	Sterylizacja ETO

Lista istotnych dostawców

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Data: 14 grudnia 2018

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Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Podwykonawca	Świadczone usługi
SteriMilano S.r.l Via Caboto, 38/40 42046 Reggio (RG) Włochy	Sterylizacja ETO
Synergy Health AST, LLC 9020 Activity Road Suite D San Diego California 92126 USA	Sterylizacja z wykorzystaniem wiązki elektronów

Certyfikat WE – System pełnego zapewnienia jakości

Historia zmian

Nr certyfikatu: CE 597884

Data: 14 grudnia 2018

Wydany dla: Becton Dickinson
Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Szwecja

Data	Nr ref	Zmiana
7 maja 2013	7974112	Pierwsze wydanie. Odzwierciedlenie CE 01141
9 stycznia 2014	8094008	Dodanie Synergy Health do listy istotnych dostawców oraz drobne zmiany adresu. Odnowienie certyfikatu
6 czerwca 2016	8543101	Dodanie Sterigenics S. de R.L. de C.V do listy istotnych dostawców
30 sierpnia 2016	8588613	Becton Dickinson India Pvt. Ltd. – poprawka w adresie dostawcy
22 listopada 2016	8314801	Rozszerzenie zakresu o sterylne opatrunki mocujące do cewników dożylnych klasy I
19 stycznia 2018	8886572	Dodanie lokalizacji projektujących oraz nowych dostawców projektujących: Carefusion 303, Becton Dickinson Infusion Therapy System Inc. i Becton Dickinson Medical Products Research & Development. Dodanie dostawcy sterylizującego SterilMilano S.r.l oraz usługi sterylizacji obecnego dostawcy Becton Dickinson Medical (S) Pte Ltd. Dodanie dostawcy wytwarzającego CareFusin BH. Zmiana nazwy na STERIS Applied Sterilization Technologies (poprzednio Synergy Health)
Obecnie	9652480	Odnowienie certyfikatu. Usunięcie nieaktualnych dostawców: Ebster s.r.o (sterylizacja ETO) Flextronics Romania S.R.L (produkcja i pakowanie Sterigenics Denmark (sterylizacja z wykorzystaniem wiązki elektronów) Sterigenics S. de R.L. de CV (sterylizacja ETO) Aktualizacja danych następujących dostawców: Sterigenics Niemcy Sterile Services (Singapore) Pte Ltd. SterilMilano STERIS Applied Sterilization Technologies (Synergy Health AST, LLC)