

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**

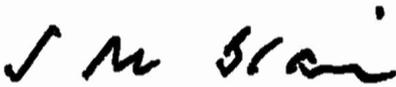
In respect of:

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2013-05-07**

Date: **2018-12-14**

Expiry Date: **2024-01-08**

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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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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	Design ETO Sterilization Manufacture Packaging

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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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Subcontractor:	Service(s) supplied
CareFusion BH 335 d.o.o. Cazin Mihaljevac bb Cazin 77220 Bosnia & Herzegovina	Manufacture Packaging
Electron Beam SDN. BHD. Lot 7 Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (FASA 2) 42920 Port Klang Selangor Malaysia	E Beam Sterilization
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization
Sterigenics US LLC 7695 Formula Place San Diego California 92121 USA	E Beam Sterilization
Sterile Service (Singapore) Pte. Ltd. No. 47A Jalan Buroh Module 6 CWT Distripark 619492 Singapore	ETO Sterilization

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Subcontractor:	Service(s) supplied
SterilMilano S.r.l Via Caboto, 38/40 42046 Reggio (RE) Italy	ETO Sterilization
Synergy Health AST, LLC 9020 Activity Road Suite D San Diego California 92126 USA	E Beam Sterilization

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Certificate History

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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
Current	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)

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