By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 506414**

Issued To: **BD Switzerland Sàrl**
Route de Crassier 17,
Business Park Terre-Bonne,
Batiment A4,
1262 Eysins
Switzerland

In respect of:

Those aspects of Annex V concerned with securing and maintaining sterile conditions in the manufacture of gravity feed administration sets for infusion and transfer and associated accessories.
Those aspects of Annex V concerned with the metrological requirements, securing and maintaining sterile conditions in the manufacture of gravity feed burette infusion administration sets and pressure sets.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2007-01-03** Date: **2021-03-03** Expiry Date: **2024-05-26**

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 506414**
Date:	**2021-03-03**
Issued To:	**BD Switzerland Sàrl** **Route de Crassier 17,** **Business Park Terre-Bonne,** **Batiment A4,** **1262 Eysins** **Switzerland**

Subcontractor:	**Service(s) supplied**
Anhui Tiankang Medical Technology Co., Ltd. No. 228 Wieyi Road Economic Development Zone Tianchang City 239300 Anhui China	**ETO Sterilization** **Manufacture**
Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland	**EU Representative**
Becton Dickinson U.K. Ltd. Building 1030 Eskdale Road Winnersh Triangle Wokingham Berkshire RG41 5TS United Kingdom	**Regulatory Compliance**

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Subcontractor:	**Service(s) supplied**
CareFusion BH 335 d.o.o. Cazin Mihaljevac bb Cazin 77220 Bosnia & Herzegovina	**Assembly** **Packaging**
CareFusion Italy 312 SpA Unipersonale Via Giacomo Matteotti 27/A Villamarzana (Rovigo) 45030 Italy	**Control of Sterilization** **Manufacture**
Centerpiece S. de R.L de C.V. Avenida de la Hospitalidad 505 Lucio Blanco Playas de Rosarito Baja California 22710 Mexico	**Assembly** **Packaging**

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Issued To:	**BD Switzerland Sàrl** **Route de Crassier 17,** **Business Park Terre-Bonne,** **Batiment A4,** **1262 Eysins** **Switzerland**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc 9120 South 150 East Sandy Utah 84070 USA	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	**Radiation (Gamma Sterilization)**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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Issued To:	**BD Switzerland Sàrl** **Route de Crassier 17,** **Business Park Terre-Bonne,** **Batiment A4,** **1262 Eysins** **Switzerland**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
ITW Ireland, trading as Filtertek, an ITW Medical Company Industrial Estate Newcastle West Co. Limerick Ireland	**Manufacture** **Packaging**
M.V. SRL Via Don G. Dossetti 5/7 Gonzaga (MN) 46023 Italy	**Assembly** **Packaging**
Providien Device Assembly, LLC Ferrocarril 17030 Interior 8, 16 & 17 Colonia Ninos Heroes Este Tijuana CP. 22120 Mexico	**Assembly** **Packaging**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Sistemas Medicos Alaris S.A. de C.V. Blvd. Insurgentes No 20351 Parque Industrial El Florido Seccion Vistas 1 Tijuana Baja California CP 22244 Mexico	**Manufacture**
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	**Radiation (E Beam Sterilization)**
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	**Radiation (E Beam Sterilization)**

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Subcontractor:	**Service(s) supplied**
Synergy Health Ede BV (Location AST Venlo) Faunalaan 38 Venlo 5928 RZ The Netherlands	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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Date: **2021-03-03**
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Switzerland

Date	Reference Number	Action
3 January 2007		First Issue.
8 May 2007		Re-issue due to the addition of Bioster S.p.A Spresiano as a subcontractor for ETO Sterilization.
18 March 2009	7316345	Re-issue due to change of company address, change of Bioster address and merging to the scope of CE 506415 into this scope.
24 June 2009	7378453	Certificate re-issue due to minor change of scope and various additions to the significant sub-contractors.
09 September 2009	7389019	Certificate re-issue due to change of company name from 'Cardinal Health Switzerland 317 Sàrl' to 'CareFusion Switzerland 317 Sàrl, also trading as Cardinal Health' Change of sub-contractors company names from 'Cardinal Health Italy, 312 S.p.A Unipersonale, Via Giacomo Matteotti 27/A, 45030 Villamarzana (Rovigo) Italy' to CareFusion Italy, 312 S.p.A Unipersonale, Via Giacomo Matteotti 27/A, 45030 Villamarzana (Rovigo) Italy' Cardinal Health France, 205 S.A.S., 5 rue Charles Lindbergh, 44110 Châteaubriant, France' to CareFusion France, 205 S.A.S., 5 rue Charles Lindbergh, 44110 Châteaubriant, France'

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Date: **2021-03-03**

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Date	Reference Number	Action
01 October 2009	7446099	Certificate re-issue due to the extension to scope to include HCH, HME, bacterial/viral retentive filters and breathing circuit accessories. Also addition of sub-contractors: ChinaMed Products (China) Ltd., JiaoTang Industrial Sone, S26113 GaoYao City, Guangdong Province, People's Republic of China. Jiangsu Kangnuo Medical Co., Ltd., No. 38 Hongfeng Road, Baimao Industrial Park, Jiangsu Province, PRC-215532, Changshu. Shanghai Amsino Medical Devices Co., Ltd., 668-5 Huajiang Road, 201803 Shanghai, People's Republic of China. Amsino Medical (Shanghai) Co., Ltd., Building #1-3, Lane 355, Huazhe Road, Songjiang Export Processing Zone, 201613 Shanghai, People's Republic of China.
21 December 2009	7464828	Certificate re-issue due to the removal of 'Jiangsu Kangnuo Medical Co., Ltd' and the extension of activity to 'Shanghai Amsino Medical Devices Co., Ltd.' To include sterilization on the significant sub-contractor.

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Switzerland

Date	Reference Number	Action
19 March 2010	7493862	Certificate re-issue due to the addition of Synergy Health (Suzhou), China for ETO Sterilization and Suzhou Addison Non-woven Product Co., Ltd, No. 168, Tong Cheng Road, Weitang Town, Xiangcheng District, 215133 Suzhou, China for Manufacture. The correction of the Isotron Nederlan B.V., Soevereinstraat 2, 4879 NN Etten-Leur, Netherlands company name to read "Nederland".
12 October 2011	7728793	1. Removal from scope the wording "and surgical gowns, drapes and packs, towels and equipment drapes" 2. Removal of sub-contractors as below: a. Synergy Health, China b. Suzhou Addison Non-Woven (2 sites), China c. Suzhou Andersen Non-Woven, China d. Suzhou Avon Textiles, China e. ProMEDICAL, China f. Sterigenics, Shanghai, China g. Sterigenics, Fleurus, Belgium h. Isotron Etten-Leur, NL i. Institute of Radiation Technique, China j. Bioster (2 sites in Italy) 3. Change of number and address of Carefusion France to 309 and addition of same as "EU Representative"

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Date	Reference Number	Action
Cont.	Cont.	4. Addition of significant sub-contractors as below: a. Isotron Nederland B.V, Netherlands – ETO Sterilization b. Sterigenics Belgium, Verviers, Belgium – ETO Sterilization c. Steril-Milano S.r.l, Italy – ETO Sterilization d. M V S.r.l, Italy – Assembly, Packaging e. Safe-Med S.r.l, Italy – Assembly, Packaging f. DKS Loversan d.o.o.,Bosnia-Herz – Assembly, Packaging 5. Correction of Carefusion Switzerland number on every page of "list of sub-contractors" to 317, not 221.
27 October 2011	7754368	Certificate renewal.
07 November 2012	7909709	1.Removal from scope the wording "The manufacture of hygroscopic condenser humidifiers (HCH), heat and moisture exchangers (HME), bacterial/viral retentive filters and breathing circuit accessories." 2.Removal from scope of "tracheotomy care kits".

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Date: **2021-03-03**
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1262 Eysins
Switzerland

Date	Reference Number	Action
Cont.	Cont.	3.Removal of sub-contractors as below: a. Amsino Medical (Shanghai) Co., Ltd, China b. Shanghai Amsino Medical Devices Co.,Ltd., China c. CareFusion France 309 S.A.S., France d. CareFusion 211, USA e. ChinaMed Products (China) Ltd, China 4.Addition of sub-contractors as below: a. Sistemas Medicos Alaris SA de C.V., Mexico for Manufacture. b. CareFusion UK 305 Ltd., United Kingdom for EU Representative, Manufacture and Regulatory Compliance. c. Steris - Isomedix Services, California 91761, USA for Gamma Sterilization 5.Corrections of Subcontractor name from Isotron Nederland B.V. to Synergy Health AST, Venlo.
30 April 2013	7974656	Change of address of Safe – MED Srl from 45024 Fiesso Umbertiano to 45039 Stienta RO, Italy.

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Switzerland

Date	Reference Number	Action
10 June 2014	8152124	Removal from certificate address the wording, "also trading as Cardinal Health". Addition of sub-contractors, 'Anhui Tiankang Medical Products Co., Ltd., No. 20 South Renhe Road, 239300 Tianchang City, Anhui Province, China', for ETO sterilization and manufacture. Addition of Control of Sterilization for CareFusion Italy, 312 S.p.A Unipersonale Villamarzana, Italy.

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Date	Reference Number	Action
01 March 2016	8481282	Correction to the certificate address, adding '10'. Change of sub-contractor name, 'DKS Loversan d.o.o Cazin, Bosnia-Herzegovine,77220', to 'Carefusion BH 335 d.o.o. Cazin'. Addition of sub-contractors: 'Covidien (Kenmex Medical Specialties), Baja California, 22500', for Manufacture; 'Integra Biotechnical, S.A. de C.V., Baja California, Mexico', for Manufacture; 'STERIS Isomedix Inc., California, 92154, USA', for Sterilization; 'Synergy Health - Applied Sterilization Technologies, LLC, California, 92126, USA', for E Beam Sterilization; 'STERIS Isomedix Services, Texas, 79936, USA', for Gamma Sterilization; 'STERIS Isomedix Services, Illinois, 60048, USA', for Gamma Sterilization; 'STERIS Isomedix Services, Utah, 84070, USA', for Gamma Sterilization; 'STERIS Isomedix Services, California, 92590, USA', for ETO Sterilization. Various formatting changes to subcontractor addresses.

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Date	Reference Number	Action
29 September 2016	8557009	Legal entity change of name and address from CareFusion Switzerland 317 Sàrl, A-One Business Centre, Zone d´activités Vers-la-Pièce no 10, Rolle, CH-1180, Switzerland to BD Switzerland Sàrl, also doing business as CareFusion Switzerland, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins. Subcontractor name and address change from Anhui Tiankang Medical Products Co Ltd, No. 20 South Renhe Road, Tianchang City, Anhui Province, 239300 China to Anhui Tiankang Medical Technology Co, Ltd. No. 228 Weiyi Road, Economic Development Zone, Tianchang City, 239300 Anhui, China. Removal of subcontractors SAFE MED S.r.l and Sterigenics Belgium. Changed the name of all Steris Isomedix Services subcontractors to Isomedix Operations Inc. Changed the name of Synergy Health - Applied Sterilization Technologies LLC to Synergy Health AST LLC.
16 December 2016	8633858	Certificate renewal: Removal of EU rep CareFusion UK 305 Ltd.

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Date	Reference Number	Action
01 March 2019	8422068	Traceable to NB 0086.
08 July 2020	9768543	Certificate Renewal, Addition of Subcontractor: Steril Milano, Via Cabato 38/40, Reggiolo, (RE), 42046, Italy. Scope wording altered from "relating to…" to "concerned with…". Change of address details: Steril Milano, Via Pompei 6, Monza (MB) 20900, Italy. Change of name and scope: Becton Dickinson UK Ltd, Building 1030, Eskdale Road, Winnersh Triangle, Wokingham, Berkshire RG41 5TS United Kingdom, and to remove Manufacturing. Removal of subcontractor: Covidien (Kennex Medical Specialties), Calle 9 Sur 125, Ciudad Industrial, Tijuana, Baja California 22500, Mexico. Removal of subcontractor: Synergy Health AST, Venlo Faunalaan 38, Venlo, 5928 RZ, The Netherlands. Change of name: Integra Biotechnical S.A. de C.V. (A Subsidiary of Providien Device Assembly LLC). Change of address details: to remove Los Pinos Business Unit and removal of Baja California. Addition of subcontractor: ITW Ireland, trading as Filtertek, an ITW Medical Company, Industrial Estate, Newcastle West, Co. limerick, Ireland.

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Date	Reference Number	Action
28 October 2020	3276337	Added subcontractor Centerpiece S. de R.L de C.V. Name of subcontractor Integra Biotechnical, S.S. de C.V changed to Providien Device Assembly, LLC Added subcontractor Synergy Health Ede BV (location AST Venlo) Added subcontractor Sterigenics US, LLC
03 March 2021	3402355	Removal of Steril Milano, Via Caboto 38/40, Reggiolo (RE), 42046, Italy Removal of Steril Milano S.r.l., Via Pompei 6, 20900 Monza (MB), Italy
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 July 2022	3601033	Addition of EU Authorised Representative: Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26 Ireland.

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Inspiring trust for a more resilient world.

11 July 2022

BD Switzerland Sàrl
Route de Crassier 17,
Business Park Terre-Bonne,
Batiment A4,
1262 Eysins
Switzerland

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 506414	93/42/EEC Annex II excluding Section 4	3601033	Addition of EU Authorised Representative: "Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland".

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

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By Royal Charter

SUSTAINABLE DEVELOPMENT GOALS