

# EC Certificate - Full Quality Assurance System

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

**No.****CE 502238****Issued To:**

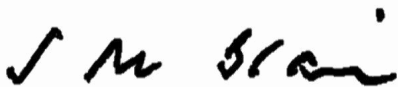
**BD Switzerland Sàrl  
Route de Crassier 17,  
Business Park Terre-Bonne,  
Batiment A4,  
1262 Eysins  
Switzerland**

**In respect of:**

**The design and manufacture of infusion systems including software for the control and monitoring of infusions and data management; sterile disposable administration sets for infusion, transfusion, enteral nutrition, parenteral nutrition and associated accessories, syringes and access devices**

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: 2005-11-16****Date: 2017-07-12****Expiry Date: 2020-11-15**

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## List of Significant Subcontractors

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

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**Switzerland**

**Subcontractor:****Service(s) supplied**

Anhui Tiankang Medical  
Technology Co, Ltd.  
No. 228 Weiyi Road  
Economic Development Zone  
Tianchang City  
239300, Anhui  
China

**ETO Sterilization  
Manufacture**

Becton Dickinson Infusion  
Therapy Systems Inc.  
9450 South State Street  
Sandy  
Utah  
84070  
USA

**Manufacture**

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**Switzerland**

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
CareFusion 303, Inc. 10020 Pacific Mesa Blvd. San Diego California 92121 USA	Design Manufacture Regulatory Compliance
CareFusion 303, Inc. 1515 Ivac Way Creedmoor North Carolina 27522 USA	Manufacture

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**Switzerland**

### Subcontractor:

### Service(s) supplied

CareFusion BH 335 d.o.o. Cazin  
 Mihaljevac bb  
 Cazin  
 77220  
 Bosnia & Herzegovina

**Assembly  
 Packaging**

CareFusion Italy  
 312 S.p.A Unipersonale  
 Via Giacomo Matteotti 27/A  
 Villamarzana  
 Rovigo  
 45030  
 Italy

**Manufacture**

CareFusion UK 305 Ltd  
 The Crescent  
 Jays Close  
 Basingstoke  
 RG22 4BS  
 United Kingdom

**EU Representative  
 Manufacture  
 Regulatory Compliance**

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Subcontractor:	Service(s) supplied
CareFusion 22745 Savi Ranch Parkway Yorba Linda California 92887 USA	Design
Clinico Medical Sp. z.o.o. ul. Kocha 1 Blonie 55-330 Poland	Manufacture Sterilization
Clinico Nanchang Ltd. Co. Qinglan Street Changbei Nanchang 330013 China	Manufacture Sterilization

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**Switzerland**

### Subcontractor:

### Service(s) supplied

Covidien  
 1222 Sherwood Road  
 Norfolk  
 Nebraska  
 68701  
 USA

**Gamma Sterilization  
 Manufacture**

Covidien  
 Calle 9 Sur 125, Ciudad Industrial  
 Tijuana  
 Baja California  
 22500  
 Mexico

**Control of Sterilization  
 Manufacture**

Flextronics Romania SRL  
 Calea Torontalului DN6, km 5.7  
 Timisoara  
 300000  
 Romania

**Manufacture**

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Subcontractor:	Service(s) supplied
Fresenius Kabi Deutschland GmbH Branch Clinico Bad Hersfeld Robert-Koch-Strasse 5 36251 Bad Hersfeld Germany	<b>Design</b> <b>Manufacture</b>
Integra Biotechnical, S.A. de C.V. Los Pinos Business Unit Avenida Ferrocarril No. 17030 Interior 8,16,17, Col. Niños Heroes Este C.P. 22120 Tijuana Baja California Mexico	<b>Manufacture</b> <b>Packaging</b>
Isomedix Operation, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	<b>Gamma Sterilization</b>

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**Subcontractor:****Service(s) supplied**

Isomedix Operations, Inc.  
1000 S. Sarah Place  
Ontario  
California  
91761  
USA

**Gamma Sterilization**

Isomedix Operations, Inc.  
2500 Commerce Drive  
Libertyville  
Illinois  
60048  
USA

**Gamma Sterilization**

Isomedix Operations, Inc.  
43425 Business Park Drive  
Temecula  
California  
92590  
USA

**ETO Sterilization**

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**Switzerland**

### Subcontractor:

### Service(s) supplied

Isomedix Operations, Inc.  
 7685 Saint Andrews Avenue  
 San Diego  
 California  
 92154  
 USA

**ETO Sterilization**

Isomedix Operations, Inc.  
 9120 South 150 East  
 Sandy  
 Utah  
 84070  
 USA

**Gamma Sterilization**

M. V. S.r.l  
 Via Don Dossetti, 5/7  
 Palidano (MN)  
 46023  
 Italy

**Assembly  
 Packaging**

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**Switzerland**

Subcontractor:	Service(s) supplied
Plexus Services RO S.R.L Eugeniu Carada Street, no 2-4 Oradea Bihor 410610 Romania	Manufacture
Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351 Parque Industrial El Florido Seccion Vistas 1 Tijuana Baja California CP 22244 Mexico	Manufacture
Steril Milano S.r.l. Via Pompei 6 Monza 20052 Italy	ETO Sterilization

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**Switzerland**

### Subcontractor:

### Service(s) supplied

Synergy Health AST, LLC  
 9020 Activity Road, Suite D  
 San Diego  
 California  
 92126  
 USA

**E beam Sterilization**

Synergy Health AST, Venlo  
 Faunalaan 38  
 Venlo  
 5928 RZ  
 The Netherlands

**ETO Sterilization**

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Date	Reference Number	Action
16 November 2005		First Issue
3 January 2007		<p>Addition of activities carried out by 'Cardinal Health Italy' formerly known as 'PlastiMedical S.p.A'</p> <p>Extension to scope to include software</p> <p>Addition of the following subcontractors; Bioster S.p.A, Tuta Healthcare Pty Limited, Primed Halberstedt, 'Cardinal Health 303, Inc. dba Cardinal Health, ALARIS® Products, Alaris Medical Systems, Inc Sistemas Medicos and Infumed.</p>
8 May 2007		Re-issue due to the addition of Bioster S.p.A Spresiano as a subcontractor for ETO Sterilization, and Clinico Medical Poland and Clinico Nanchang as subcontractors for manufacture and ETO Sterilization
18 March 2009	7316344	Re-issue due to change of company address, transfer of Tyco, Ballymoney, activities to Covidien, Commerce, change of address for Cardinal Health 303, Tuta Healthcare and Bioster, and addition of M.V. S.r.l. and Bluservice as subcontractors for assembly and packaging.

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Date	Reference Number	Action
09 September 2009	7389012	Change of company name from Cardinal Health to CareFusion, also trading as Cardinal Health. Change of Cardinal Health sub-contractors names to CareFusion, except Mexico.
20 August 2010	7546482	Re-issue due to the addition of Isotron Nederland B.V. Venlo as a sub contractor for ETO Stelization
15 November 2010	7602104	<p>Certificate reissue</p> <p>Addition of Sterigenics (Petit Rechain) as a sub contractor for ETO Sterilization. Removal of sub contractor Bioster S.p.A (Spresiano and Calciate).</p> <p>Addition of CareFusion UK 305 Ltd as the EU Representative.</p> <p>Correction of previous certificate expiry date as dated 20 August 2015.</p> <p>Rename of Covidien to Kendall, addition of Kendall, 15 Hampshire Street, Mansfield, MA 02048, USA as a significant sub contractor for Design.</p> <p>Update of various addresses</p>

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Date	Reference Number	Action
29 March 2011	7645412	<p>The following changes were made to the list of significant subcontractors:</p> <ul style="list-style-type: none"> <li>- Addition of Medegen, CA, 91761, for design</li> <li>- Subcontactor name "Bluservice, Di Braidia Maria Azzurra, EC.S.A.S", changed to "SAFE – MED S.r.l."</li> <li>- Removal of Infumed, Germany</li> <li>- Addition of Steris Isomedix, CA 92590, for ETO Sterilization</li> <li>- Addition of Steris Isomedix, CA 91761, for Gamma Sterilization</li> <li>- Addition of Steris Isomedix, CA 92154, for ETO Sterilization</li> <li>- Addition of Cardinal Health, TX 79906, for Gamma Sterilization</li> <li>- Addition of BeamOne, CA 92126, for E beam Sterilization</li> <li>- Removal of design activities from CareFusion UK 305</li> <li>- Removal of CareFusion 303 creedmore</li> </ul>

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Date	Reference Number	Action
14 September 2011	7728794	Addition of two new subcontractors: - Steril-Milano s.r.l, Monza for ETO Sterilization - DKS Loversan d.o.o, Cazin for Assembly and Packaging. Change of activity for Safe-Med s.r.l from "Purchasing" to "Packaging" Removal of BMDi Tuta Healthcare as significant subcontractor.
31 October 2012	7904051	Addition of two new subcontractors: - Amsino Medical (Kunshan) Co. Ltd for Manufacture and ETO Sterilisation - Integra Biotechnical, SA de C.V. for Manufacture and Packaging Change of Company name for subcontractors: - Beam One, San Diego, California, 92126 USA to Synergy Health - Isotron Nederland B.V., Venlo, 5982 RZ, Netherlands to Synergy Health. Re-issue due to minor amendment to a subcontractor address.

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Date	Reference Number	Action
30 April 2013	7974658	Change of address of Safe - MED Srl, from 45024 Fiesso Umbertino to 45039 Stienta RO Italy
06 December 2013	8082847	Re-issue due to the deletion of, 'also trading as Cardinal Health', from the certificate address. Addition of, 'Plexus Services RO S.R.L, Calea Borsului, Nr. 34/A, Oradea, 410605, Bihor, Romania', as subcontractor for manufacture.
18 June 2014	8165227	Minor change- Add subcontractor Covidien 22500 Tijuana B.C. Mexico. Clarification of services for Kendall at 400 Maple St. Commerce: Gamma Sterilization deleted and replaced with Control of Sterilization.

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Date	Reference Number	Action
08 July 2015	8364530	Reissue due to Removal of sub contractor Integra Biotechnical LLC, Mexico for Manufacture & Packaging. Removal of sub contractor Cardinal Health for Sterilization. Removal of sub contractor Kendall Texas for Manufacture & Control of Sterilization. Removal of sub contractor Medegen for Design. Addition of sub contractor STERIS Isomedix Services, Texas for ETO Sterilization & Gamma Sterilization. Change of sub contractor address for Plexus Services RO S.R.L for manufacture. Change of sub contractor address for Integra Biotechnical, S.A. de C.V. Mexico for manufacture & Packaging. Addition of sub contractor Flextronics Romania SRL for manufacture. Addition of sub contractor Covidien Norfolk, USA for manufacture and Gamma sterilization.

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Date	Reference Number	Action
09 September 2015	8360474	<p>Certificate renewal and addition of four subcontractors; CareFusion 303, 1515 Ivac Way, Creedmoor, NC 27522; CareFusion, 22745 Savi Ranch Parkway, Yorba Linda, CA, 92887. STERIS Isomedix Services, 2500 Commerce Drive, Libertyville, IL 60048; STERIS Isomedix Services, 9120 South 150 East, Sandy, UT 84070.</p> <p>Also, subcontractor DKS Loversan d.o.o. Cazin name change to CareFusion BH 335 d.o.o. Cazin.</p> <p>Also, removal of two subcontractors; Beam One, 9020 Activity Road, Suite D, San Diego, CA 92126; Kendall, a division of Tyco, Healthcare Group LP, 15 Hampshire Street, Mansfield, MA 02048</p>

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29 September 2016	8557006	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. Added subcontractor Anhui Tiankang Medical Technology Co, Ltd. Subcontractors Primed Halberstadt, SAFE MED, Sterigenics Belgium and Amsino Medical (Kunshan) Co Ltd removed. 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.
Current	8768150	Addition of subcontractor Becton Dickinson Infusion at locations Sandy Utah and Nogales Mexico, removal of 'also doing business as CareFusion' from name.

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