

# EC Certificate - Full Quality Assurance System

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

**No.**

**CE 502238**

Issued To:

**CareFusion Switzerland 317 Sàrl  
A-One Business Centre  
Zone d'activités  
Vers-la-Pièce no 10  
Rolle  
CH-1180  
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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **16 November 2005**

Date: **09 September 2015**

Expiry Date: **15 November 2020**

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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

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Subcontractor:	Service(s) supplied
Amsino Medical (Kunshan) Co. Ltd 582 Lidu Road QuiadengTown Kunshan City 215343 China	ETO Sterilization 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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Subcontractor:	Service(s) supplied
CareFusion BH 335 d.o.o. Cazin Mihaljevac bb Cazin 77220 Bosnia & Herzegovina	<b>Assembly</b> <b>Packaging</b>
CareFusion Italy 312 S.p.A Unipersonale Via Giacomo Matteotti 27/A Villamarzana Rovigo 45030 Italy	<b>Manufacture</b>
CareFusion UK 305 Ltd The Crescent Jays Close Basingstoke RG22 4BS United Kingdom	<b>EU Representative</b> <b>Manufacture</b> <b>Regulatory Compliance</b>

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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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Subcontractor:	Service(s) supplied
Covidien 1222 Sherwood Road Norfolk Nebraska 68701 USA	<b>Gamma Sterilization Manufacture</b>
Covidien Calle 9 Sur 125, Ciudad Industrial Tijuana Baja California 22500 Mexico	<b>Control of Sterilization Manufacture</b>
Flextronics Romania SRL Calea Torontalului DN6, km 5.7 Timisoara 300000 Romania	<b>Manufacture</b>

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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>
M. V. S.r.l Via Don Dossetti, 5/7 Palidano (MN) 46023 Italy	<b>Assembly</b> <b>Packaging</b>

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Subcontractor:	Service(s) supplied
Plexus Services RO S.R.L Eugeniu Carada Street, no 2-4 Oradea Bihor 410610 Romania	<b>Manufacture</b>
Primed Halberstadt Medizintechnik GmbH Strasse des 20. Juli 1 38820 Halberstadt Germany	<b>Design Manufacture</b>
SAFE - MED S.r.l Via Del Lavoro 209 Zona Artigianale Stienta RO 45039 Italy	<b>Assembly Packaging</b>

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Subcontractor:	Service(s) supplied
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
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue du Parc, 29 Verviers B-4800 Belgium	ETO Sterilization
Steril Milano S.r.l. Via Pompei 6 Monza 20052 Italy	ETO Sterilization

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Subcontractor:	Service(s) supplied
STERIS Isomedix Services Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
STERIS Isomedix Services 1000 South Sarah Place Ontario California 91761 USA	Gamma Sterilization
STERIS Isomedix Services 1435 Isomedix Place Vista Del Sol Industrial Park El Paso Texas 79936 USA	ETO Sterilization Gamma Sterilization

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Subcontractor:	Service(s) supplied
STERIS Isomedix Services 2500 Commerce Drive Libertyville Illinois 60048 USA	Gamma Sterilization
STERIS Isomedix Services 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization
STERIS Isomedix Services 9120 South 150 East Sandy Utah 84070 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health - Applied Sterilization Technologies, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	<b>E beam Sterilization</b>
Synergy Health AST, Venlo Faunalaan 38 5928 RZ Venlo Netherlands	<b>ETO Sterilization</b>

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