

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2005-11-16**

Date: **2020-06-23**

Expiry Date: **2024-05-26**

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Page 1 of 3

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Supplementary Information to CE 502238

Issued To:

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GMDN	Device Description	Intended Purpose
Class IIb		
13215	Alaris™ Volumetric Pumps	The Alaris™ Volumetric Pumps are intended for use by medical staff for the purpose of controlling infusion rate and volume
13217	Alaris™ Syringe Pumps	The Alaris™ Syringe Pumps are intended for use by medical staff for the purpose of controlling infusion rate and volume
47903	Alaris™ Editor	Alaris™ Editor is a PC-based application that allows hospitals to develop best practice data sets of IV medication dosing guidelines and configure general pump settings

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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NBOG code(s)	Device Description	Intended Purpose
Class IIa		
MD 0102	IV administration sets, Infusion sets, transfusion sets, access devices, connectors, Manifolds, Stopcocks	N/A
MD 1101	Alaris™ Enteral Plus Syringe Pump	N/A

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List of Significant Subcontractors

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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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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

Becton Dickinson San Diego
 10020 Pacific Mesa Blvd.
 San Diego
 California
 92121
 USA

**Design
 Regulatory Compliance**

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Subcontractor:**Service(s) supplied**

Becton Dickinson U.K. Ltd.
Building 1030
Eskdale Road
Winnersh Triangle
Wokingham Berkshire
RG41 5TS
United Kingdom

Regulatory Compliance

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

**Control of Sterilization
Manufacture**

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Subcontractor:**Service(s) supplied**

Connor Solutions Ltd.,
Gadwall Road
Rainton Bridge
South Business Park
Houghton-Le-Spring
Tyne and Wear
DH4 5NL
UK

Manufacture

Flextronics International Kft.
Hangár u. 5-37
Budapest
H-1183
Hungary

Manufacture

Flextronics Romania S.R.L
Calea Torontalului DN6, km 5.7
RO-300000 Timisoara
Romania

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Subcontractor:	Service(s) supplied
Integra Biotechnical, S.A. de C.V. (A Subsidiary of Providien Device Assembly, LLC) Ferrocaril 17030 Interior 8, 16 & 17, Colonia Ninos Heroes Este CP. 22120 Tijuana Mexico	Manufacture Packaging
Isomedix Operations, Inc 1435 Isomedix Place El Paso Texas 79936 USA	Radiation (Gamma Sterilization)
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	Radiation (Gamma Sterilization)

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Subcontractor:**Service(s) supplied**

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

Radiation (Gamma Sterilization)

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

ETO Sterilization

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

ETO Sterilization

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Switzerland

Subcontractor:**Service(s) supplied**

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

Radiation (Gamma Sterilization)

ITW Ireland, trading as Filtartek, an ITW Medical
Company
Industrial Estate
Newcastle West
Co. Limerick
Ireland

**Manufacture
Packaging**

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

**Assembly
Packaging**

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Subcontractor:**Service(s) supplied**

MIPM Mammendorfer Institut für Physik und Medizin
GmbH
Oskar-von-Miller Strasse 6
Mammendorf
82291
Germany

Design
Manufacture

Plexus Services RO S.R.L
Eugeniu Carada Street, no 2-4
Oradea
Bihor
410610
Romania

Manufacture

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

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Subcontractor:**Service(s) supplied**

Steril Milano
Via Caboto 38/40
Roggiolo (RE)
42046
Italy

ETO Sterilization

Steril Milano S.r.l.
Via Pompei, 6
20900 Monza (MB)
Italy

ETO Sterilization

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

Radiation (E Beam Sterilization)

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Date	Reference Number	Action
16 November 2005		First Issue.
3 January 2007		Addition of activities carried out by 'Cardinal Health Italy' formerly known as 'PlastiMedical S.p.A' Extension to scope to include software 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.
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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29 March 2011	7645412	<p>The following changes were made to the list of significant subcontractors:</p> <ul style="list-style-type: none">- Addition of Medegen, CA, 91761, for design- Subcontractor name "Bluservice, Di Braid Maria Azzurra, EC.S.A.S", changed to "SAFE – MED S.r.l."- Removal of Infumed, Germany- Addition of Steris Isomedix, CA 92590, for ETO Sterilization- Addition of Steris Isomedix, CA 91761, for Gamma Sterilization- Addition of Steris Isomedix, CA 92154, for ETO Sterilization- Addition of Cardinal Health, TX 79906, for Gamma Sterilization- Addition of BeamOne, CA 92126, for E beam Sterilization- Removal of design activities from CareFusion UK 305- Removal of CareFusion 303 creedmore

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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.
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.</p> <p>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>
29 September 2016	8557006	<p>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.</p> <p>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.</p>

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Date	Reference Number	Action
12 July 2017	8768150	Addition of subcontractor Becton Dickinson Infusion at locations Sandy Utah and Nogales Mexico, removal of 'also doing business as CareFusion' from name.
01 March 2019	8422068	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Clinico Medical Sp. z.o.o from 'Sterilization' to 'ETO Sterilization'. Clinico Nanchang Ltd. Co. from 'Sterilization' to 'ETO Sterilization'.

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Date	Reference Number	Action
Current	9768538	<p>Certificate renewal.</p> <p>Addition of the following subcontractors:</p> <p>Connor Solutions Limited., Tyne and Wear, UK.</p> <p>Flextronics International Kft., Budapest, Hungary.</p> <p>ITW Ireland trading as Filtertek, an ITW Medical Company, Ireland.</p> <p>MIPM Mammendorfer Institut für Physik und Medizin GmbH, Mannendorf, Germany.</p> <p>Removal of the following subcontractors:</p> <p>Carefusion, Yorba Linda, CA, USA.</p> <p>Carefusion 303 Inc, Creedmoor, USA.</p> <p>Clinico Medical Sp. Z.o.o. Blonie, Poland.</p> <p>Clinico Nanchang Ltd., Co., Nanchang, China.</p> <p>Covidien, Norfolk, Nebraska, USA.</p> <p>Covidien, Tijuana, Mexico.</p> <p>Fresenius Kabi Deutschland GmbH, Bad Hersfeld, Germany.</p> <p>Synergy Health AST, Venlo, The Netherlands.</p> <p>Update of address details for the following subcontractors:</p> <p>Flextronics Romania SRL, Timisoara, Romania.</p> <p>M.V.S.r.l, Ginzaga, Italy.</p> <p>Steril Milano S.r.l Via Pompei 6, Italy.</p>

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Date	Reference Number	Action
	9768538	<p>Integra Biotechnical S.A. de C.V., Tijuana, Mexico.</p> <p>Change in services for the following subcontractors:</p> <p>Carefusion 303, Inc., San Diego, USA – removal of manufacturing.</p> <p>Carefusion Italy 312, Villamarzana, Italy – addition of Control of sterilization</p> <p>Becton. Dickinson UK Ltd. – removal of EU representative and manufacturing.</p> <p>Change of name for the following subcontractors:</p> <p>Becton Dickinson UK Ltd.</p> <p>Becton Dickinson San Diego.</p> <p>Integra Biotechnical S.A. de C.V. (a subsidiary of Providien Device Assembly LLC).</p> <p>Addition of device table.</p>

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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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