Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	BD Switzerland Sàrl
Manufacturer address and contact details	Route de Crassier 17 Business Park Terre-Bonne Bâtiment A4 1262 Eysins Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000026539

Authorised Representative name (if applicable)	Becton Dickinson Ireland Ltd
Authorised Representative address and contact details	Becton Dickinson Ireland Ltd. Donore Road Drogheda, Co. Louth A92 YW26 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000007610

Notified body name (if applicable)	BSI Group The Netherlands B.V. □ See attached schedule
Notified body number (if applicable)	2797 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 502238 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024 □ See attached schedule
End date of extended validity/transition period	31 December 2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

✓ Expired/expires *after* 20 March 2023:

✓ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

✓ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

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

Manoja Ranawake
Vice President, Regulatory Affairs - EMEA,
WWIPD & OUS Infection Prevention

DocuSigned by:
Manoja Ranawake
Signer Name: Manoja Ranawake
Signing Reason: I approve this document
Signing Time: 29-Apr-2024 | 2:53:57 AM PDT
2AD6595CC68E40A7BDC5BF23CE303120

Contact Details (at least email): manoja.ranawake@bd.com

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
GPneXus1	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
CCneXus1	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
CCneXus1-S	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
9003TIG03-G	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
PKneXus1	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02193	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02159	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02198	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02196	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02197	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
1000SP02156	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-30	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-32	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

80300UNS01-33	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-34	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-035	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-50	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-52	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-53	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-54	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-235	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-70	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-72	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-73	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-74	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS01-92	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-30	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-32	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-33	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-34	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-035	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-50	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-52	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-53	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-54	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

80300UNS02-235	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-70	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-72	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-73	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-74	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80300UNS02-92	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-30	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-32	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-33	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-34	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-035	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-50	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-52	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-53	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-54	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-235	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-70	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-72	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-73	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-74	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A
80223UNS02-92	CE 502238	26 May 2024	BSI Netherlands 2797	BSI Netherlands 2797	31 December 2028	N/A

By Royal Charter

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; MRI compatibility accessory, 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: **2021-03-18** Expiry Date: **2024-05-26**

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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
57967	Alaris™ Communication Engine	Alaris™ Communication Engine (ACE) is software application intended to transfer datasets to, and infusion data from, compatible BD infusion products via a network connection.

First Issued: **2005-11-16** Date: **2021-03-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 502238

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Switzerland

GMDN	Device Description	Intended Purpose
36179	Alaris™ Gateway Workstation	The Alaris™ Gateway Workstation is intended to be used within the hospital environment to provide mounting, power and communication support to the compatible Alaris™ infusion pumps. The Workstation transmits infusion data for the purpose of record keeping and pump alarm monitoring.
38371	BD Alaris™ MRI Capsule	The BD Alaris™ MRI Capsule is intended to be used to protect the MRI images from RF wave interference and also prevent the MRI Scanner from attracting infusion pumps to the magnet.

First Issued: **2005-11-16** Date: **2021-03-18** Expiry Date: **2024-05-26**

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Supplementary Information to CE 502238

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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

First Issued: **2005-11-16** Date: **2021-03-18** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

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

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

Issued To: **BD Switzerland Sàrl**
Route de Crassier 17,
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Switzerland

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	Certificate reissue. Addition of Sterigenics (Petit Rechain) as a sub contractor for ETO Sterilization. Removal of sub contractor Bioster S.p.A (Spresiano and Calcinate). Addition of CareFusion UK 305 Ltd as the EU Representative. Correction of previous certificate expiry date as dated 20 August 2015. Rename of Covidien to Kendall, addition of Kendall, 15 Hampshire Street, Mansfield, MA 02048, USA as a significant sub contractor for Design. Update of various addresses.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

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

Date	Reference Number	Action
29 March 2011	7645412	The following changes were made to the list of significant subcontractors: - Addition of Medegen, CA, 91761, for design - Subcontactor name "Bluservice, Di Braida 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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Route de Crassier 17,
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1262 Eysins
Switzerland

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

Issued To: **BD Switzerland Sàrl**
Route de Crassier 17,
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Batiment A4,
1262 Eysins
Switzerland

Date	Reference Number	Action
30 April 2013	794658	Change of address of Safe – MED Srl, from 45024 Flesso Umbertiano 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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

Issued To: **BD Switzerland Sàrl**
Route de Crassier 17,
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Batiment A4,
1262 Eysins
Switzerland

Date	Reference Number	Action
09 September 2015	8360474	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. Also, subcontractor DKS Loversan d.o.o. Cazin name change to CareFusion BH 335 d.o.o. Cazin. 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.
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.

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EC Certificate - Full Quality Assurance System Certificate History

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Batiment A4,
1262 Eysins
Switzerland

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'.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

Issued To: **BD Switzerland Sàrl**
Route de Crassier 17,
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Switzerland

Date	Reference Number	Action
23 June 2020	9768538	Certificate renewal. Addition of the following subcontractors: Connor Solutions Limited., Tyne and Wear, UK. Flextronics International Kft., Budapest, Hungary. ITW Ireland trading as Filtertek, an ITW Medical Company, Ireland. MIPM Mammendorfer Institu fur Physik und Medizin GmbH, Mannendorf, Germany. Removal of the following subcontractors: Carefusion, Yorba Linda, CA, USA. Carefusion 303 Inc, Creedmoor, USA. Clinico Medical Sp. Z.o.o. Blonie, Poland. Clinico Nanchang Ltd., Co., Nanchang, China. Covidien, Norfolk, Nebraska, USA. Covidien, Tijuana, Mexico. Fresenius Kabi Deutschland GmbH, Bad Hersfeld, Germany. Synergy Health AST, Venlo, The Netherlands. Update of address details for the following subcontractors: Flextronics Romania SRL, Timisoara, Romania. M.V.S.r.l, Ginzaga, Italy. Steril Milano S.r.l Via Pompei 6, Italy.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-03-18**

Issued To: **BD Switzerland Sàrl**
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Switzerland

Date	Reference Number	Action
	9768538	Integra Biotechnical S.A. de C.V., Tijuana, Mexico. Change in services for the following subcontractors: Carefusion 303, Inc., San Diego, USA – removal of manufacturing. Carefusion Italy 312, Villamarzana, Italy – addition of Control of sterilization Becton. Dickinson UK Ltd. – removal of EU representative and manufacturing. Change of name for the following subcontractors: Becton Dickinson UK Ltd. Becton Dickinson San Diego. Integra Biotechnical S.A. de C.V. (a subsidiary of Providien Device Assembly LLC). Addition of device table.
03 March 2021	3402356	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

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502238**

Date: **2021-03-18**

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

Date	Reference Number	Action
18 March 2021	3280468	Added MRI compatibility accessory to scope. Added Alaris™ Communication Engine, Alaris™ Gateway Workstation and BD Alaris™ MRI Capsule to device table. Added subcontractor Centerpiece S. de R.L de C.V. for Assembly and Packaging Added subcontractor Synergy Health Ede BV (location AST Venlo) for ETO Sterilization. Added subcontractor Sterigenics US, LLC for E-Beam Sterilization. Changed address of Integra Biotechnical, S.S. de C.V. (A Subsidiary of Providien Device Assembly, LLC) from Ferrocarril 17030 Interior 8, 16 & 17 to Privada Los Pinos 17030 Interior 3, 16 & 17. Changed role of Integra Biotechnical, S.S. de C.V. (A Subsidiary of Providien Device Assembly, LLC) from Manufacture and Packaging to Assembly and Packaging. Corrected address of subcontractor Isomedix Operations, Inc. from Temeluca to Temecula.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
06 May 2022	3601032	Addition of EU Authorised Representative: Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26 Ireland.

By Royal Charter

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Date	Reference Number	Action
30 October 2022	3775296	Addition of BD Research Centre Ireland Limited, National Technology Park, Limerick, V94 V500, Ireland. Service(s) supplied: Design. Addition of: BD Hermosillo S.A. de C.V., Blvd. Antonio Quiroga No. 107 G y H, Col. Vista Bella, Hermosillo, Sonora, C.P. 83174, Mexico Removal of service (Regulatory Compliance) from Becton Dickinson San Diego, 10020 Pacific Mesa Blvd., San Diego, California, 92121, USA
05 December 2022	3811857	Amended - Removal of subcontractor pages Amended – addition of subcontractor Sterigenics Belgium (Petit-Rechain) SA, Liege (activity: ETO sterilization)
30 November 2023	30009574	Approval of three critical subcontractors (activity: gamma sterilization)

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product	Syringe Pump
Name and address of the applicant	Becton Dickinson National Technology Park, Plassey, Co. Limerick, V94 V500, Ireland
Name and address of the manufacturer	Becton Dickinson Switzerland Sarl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
Name and address of the factory Note: *When more than one factory, please report on page 2*	☐ Additional information on page 2 Plexus Services RO S.R.L Eugeniu Carada Street, No 2-4, Oradea, 410610, Bihor, Romania
Ratings and principal characteristics	115 – 230 V~, 50-60 Hz, 30 VA Battery: 7.2 Vdc, 2.7 Ah
Trademark (if any)	Alaris™
Customer's Testing Facility (CTF) Stage used	
Model / Type Ref.	CCneXus1-S and CCneXus1
Additional information (if necessary may also be reported on page 2)	☐ Additional information on page 2 - No mains cables / cord-sets were assessed under this submission. The equipment was accepted on the basis that the installation instructions continue to state the use of only an appropriately rated and approved supply cable / cord-set in accordance with the regulations of the country it is used in. The equipment was not evaluated for use within an Oxygen Rich Environment. In addition, all applicable Clauses of IEC 62304 have be addressed in report TRA-040768-34-00A. In addition, all applicable Clauses of IEC 62366 have be addressed in report TRA-040768-34-03A.
A sample of the product was tested and found to be in conformity with	IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-2-24:2012 National differences: US Comments: EMT certification reference ; GU-BDIQ-0004
As shown in the Test Report Ref. No. which forms part of this Certificate	TRA-040768-34-00A, TRA-040768-34-01A, TRA-040768-34-02A, TRA-040768-34-03A

This CB Test Certificate is issued by the National Certification Body

Element Materials Technology
Unit 1 Pendle Place, Skelmersdale, West Lancashire WN8 9PN, United Kingdom

Date: 2020-11-04

Signature: Stephen Winsor

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: **MD 71300**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, installation and servicing of infusion systems including infusion pumps, syringe pumps, enteral feeding pumps and reusable accessories; software for the control and monitoring of infusions and data management; and sterile and non-sterile devices for infusion preparation and delivery including syringes, tubular devices, adapters, connectors, ramps, stopcocks, and caps.
The sales and distribution of medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-12-20
Latest Revision Date: 2024-02-08

Effective Date: 2021-12-07
Expiry Date: 2024-12-06

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