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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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**

EC Certificate - Full Quality Assurance System

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**

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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

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1262 Eysins
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.

EC Certificate - Full Quality Assurance System Certificate History

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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

EC Certificate - Full Quality Assurance System Certificate History

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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.

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Switzerland

Date	Reference Number	Action
30 April 2013	7974658	Change of address of Safe - MED Srl, from 45024 Fiesso 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.

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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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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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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	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

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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.

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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)

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05 December 2022

BD Switzerland Sàrl
Route de Crassier 17,
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Batiment A4,
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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 502238	93/42/EEC Annex II excluding Section 4	3811857	Amended - Removal of subcontractor pages Amended – addition of subcontractor Sterigenics Belgium (Petit-Rechain) SA, Liege (activity: ETO sterilization)

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

By Royal Charter

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number: **MD 533787**

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

The manufacturing and testing of printed circuit board assemblies, box assemblies of medical products and assembly, test and packaging of sterile and non-sterile medical disposable products.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2008-03-18
Effective Date: 2023-03-19
Latest Revision Date: 2023-03-17
Expiry Date: 2026-03-18

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MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
248692-2017-AQ-USA-NA-PS

Initial certification date:
21 April, 2010

Valid:
11 July, 2022 – 10 July, 2025

This is to certify that the management system of

Plexus Services RO S.R.L.

Eugeniu Carada Street, no 2 – 4, Oradea, 410610, Bihor, Romania

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

The Sale and Distribution of Contract Manufacturing Services, including Production, Test, and Servicing of Printed Circuit Board Assemblies, High Level Assemblies and Finished Devices listed below. High level Assemblies are mechanical, electro-mechanical, pneumatic, optical and packaging types of assemblies. List of Finished Medical Devices manufactured at Plexus Oradea site: - TCM5 continuously monitor tcpO2 for ICU patients. - Infusion pumps

Place and date:
Høvik, 27 June, 2022

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

EC Declaration of Conformity to: Medical Devices Directive 93/42/EEC

Legal Manufacturer:	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
Manufacturing Site (s):	CareFusion BH 335 d.o.o Cazin, Mihaljevac bb, Cazin, 77220, Bosnia & Herzegovina. Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351, Parque Industrial, El Florido Seccion Vistas 1, Tijuana, Baja California, CP 22244, Mexico.
Device Description/Family:	Alaris™ GP Infusion Sets *(See attached Product Schedule)*
EC Product Classification:	Class IIa, Annex IX, Rule 2
GMDN:	*35833 – Infusion Pump Administration Set* A dedicated infusion administration set used to deliver intravenous solutions from the infusion pump to the infusion site. *38569 – Blood transfusion set* An intravascular administration set used to administer blood from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, and I.V. stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Applied Directives:	85/374/EEC - Product Liability 2006/121/EC – REACH 94/62/EC - Packaging and Packaging Waste Directive

Applied Standards	BS EN 556-1:2001/AC:2006 BS EN 1041:2008 +A1:2013 BS EN ISO 1135-5:2015 BS EN ISO 8536-4:2013 +A1:2013 BS EN ISO 8536-5:2013 BS EN ISO 8536-8:2015 BS EN ISO 8536-9:2015 BS EN ISO 8536-10:2015 BS EN ISO 8536-11:2015 BS ISO 8536-12:2007 +A1:2013

DOCO Use Only: Support Number 0310-010-002-R, DIR 100000236720, Part 000, Type DQS, Version 02 CO16401 Release Date: 23/Nov/2017

	BS EN ISO 10993-1:2009 BS EN ISO 10993-4:2017 BS EN ISO 10993-5:2009 BS EN ISO 10993-7:2008 BS EN ISO 10993-10:2013 BS EN ISO 10993-11:2009 BS EN ISO 11135:2014 BS EN ISO 11737-1:2018 BS EN ISO 11737-2:2009 BS EN ISO 11607-1:2009 +A1:2014 BS EN ISO 11607-2:2006 +A1:2014 BS EN ISO 13485:2016/AC:2016 BS EN ISO 14644-1:2015 BS EN ISO 14644-2:2015 BS EN ISO 14644-5:2004 BS EN ISO 14971:2012 BS EN ISO 15223-1:2016/AC:2017 BS EN 15986:2011 ISO 594-1:1986 ISO 594-2:1998 ISTA-1A - 2014 Edition ISTA-2A - 2012 Edition
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Notified Body Number: 2797 Former Notified Body: BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP. Notified body number 0086
CE Certificate Number:	*Annex II (EC Certificate No. 502238)*
Date of issuance of original CE certificate:	16 November 2005

STED File: 003

Issue Level: 45

Signed: Nesli

Date: 17 Jan 2020

Nesli Karakaya

Director, Regulatory Affairs
WW Infusion Speciality Disposables

DOCO Use Only: Support Number 0310-010-002-R, DIR 100000236720, Part 000, Type DQS, Version 02 CO16401 Release Date: 23/Nov/2017

Product Schedule
Alaris™ GP Infusion Sets

Mexico

Part Number	Description	EC Product Class	GMDN
60033E	Alaris™ Products. Alaris™ GP Volumetric Pump. SmartSite™ Needle-free System. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING (PE/PVC). 0.2 µm FILTER.	II a	35833
60103E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. BURETTE SET. NO FILTER.	II a	35833
63110V	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. SPLIT SEPTUM INJECTION PORT(S). NO FILTER.	II a	35833
63260NY	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING (PE/PVC). NO FILTER.	II a	35833
63280NY	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. SYRINGE ADAPTER. NO FILTER.	II a	35833
63441E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. BURETTE SET. NO FILTER.	II a	35833

DOCO Use Only: Support Number 0310-010-002-R, DIR 100000236720, Part 000, Type DQS, Version 02 CO16401 Release Date: 23/Nov/2017

CareFusion 335, Bosnia

Part Number	Description	EC Product Class	GMDN
60093E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	II a	35833
60123E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 1.2 µm FILTER.	II a	35833
60173E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	II a	35833
60393E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION / BLOOD SET. 200 µm FILTER.	II a	38569
60593	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	II a	35833
60643	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.	II a	35833
60693	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	II a	35833
60693E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	II a	35833
60793	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	II a	35833
60793E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	II a	35833
60894	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.	II a	38569
60895	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.	II a	38569
60903	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	II a	35833
60980	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.	II a	38569
60950E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	II a	35833

DOCO Use Only: Support Number 0310-010-002-R, DIR 100000236720, Part 000, Type DQS, Version 02 CO16401 Release Date: 23/Nov/2017

Part Number	Description	EC Product Class	GMDN
60951E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	II a	35833
60952E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.	II a	35833
60953V	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 µm FILTER.	II a	35833
63200NYB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. NO FILTER.	II a	35833
63401EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	II a	35833
63402BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	II a	35833
63420EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	II a	35833
63423BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	II a	35833
63477EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.	II a	38569
G59593F	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	II a	35833
G59693FE	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	II a	35833

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EC Declaration of Conformity to:
Medical Devices Directive 93/42/EEC

Legal Manufacturer:	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
EU Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Manufacturing Site (s):	Plexus RO S.R.L Eugeniu Carada Street, no 2–4, Oradea, 410610, Bihor, Romania
Device Description/Family:	Alaris™ GH Syringe Pump *(See attached Product Schedule)*
EC Product Classification:	Class IIb, Annex IX, Rule 11
GMDN:	*13217 – Syringe Pump* A mains electricity (AC-powered) device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution (e.g., 0.1 ml/hr), it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia. It will typically have internal batteries that allow the device to operate for a short period of time when no line power is available (e.g., during transport or a power outage).

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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Applied Standards and Directives:	- *Medical Device Directive 93/42/EEC* - *EMC Directive 2014/30/EU* - *RoHS Directive 2011/65/EU with amendment: Commission Delegated Directive 2015/863* - *Machinery Directive 2006/42/EC* - *Waste electrical and electronic equipment 2002/96/EC* - *Product Liability 85/374/EEC* - *REACH 1907/2006* - *Packaging and Packaging Waste Directive 94/62/EC* - *Battery 2006/66/EC* - *Electronic Instructions for Use of Medical Devices 207/2012* - *EN ISO 13485:2016* - *EN ISO 14971:2012* - *IEC 60601-1:2005 +A1:2012* - *IEC 60601-1-2:2014* - *IEC 60601-1-6:2010 +A1:2013* - *IEC 62366:2007 +A1:2014* - *IEC 60601-1-8:2006 +A1:2012* - *IEC 60601-2-24:2012* - *IEC 62304:2006* - *EN ISO 15223-1:2016* - *EN 1041:2008+A1:2013* - *IEC 60529:1989+A1:1999+A2:2013* - *EN 1789:2007 +A2:2014* - *ISTA-1A-2014 Edition*
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Notified Body Number: 2797 Former Notified Body: BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP. Notified body number 0086
CE Certificate Number:	*Annex II (EC Certificate No. 502238)*
Date of issuance of original CE certificate:	16 November 2005

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STED File: 009

Issue Level: 25

Signed:

DocuSigned by:

Ondina Bennaim

Signer Name: Ondina Bennaim
Signing Reason: I approve this document
Signing Time: 08-Aug-2023 | 2:39:46 AM PDT

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Ondina Bennaim

Date: 08-Aug-2023

Senior Director Regulatory Affairs
International Infusion

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Product Schedule
Alaris™ GH Syringe Pump

GMDN Number: 13217

Part Number	Description	EC Product Class
8002TIG03	Alaris™ GH Plus Syringe Pump	IIb
8002TIG03-G	Alaris™ GH Plus Guardrails™ Syringe Pump	IIb
8002TIG01-CHINA	Alaris™ GH Plus Syringe Pump For China	IIb

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