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):	Flextronics Romania SRL Calea Torontalului DN6, km 5.7 Timisoara, 300000, Romania
Device Description/Family:	Alaris™ GP Volumetric Pump *(See attached Product Schedule)*
EC Product Classification:	Class IIb, Annex IX, Rule 11
GMDN:	*13215 – Infusion Pump, general purpose* A mains electricity (AC-powered) device designed to facilitate the accurate and consistent administration of drugs and solutions which can be delivered via intravenous, subcutaneous, arterial, epidural, and intracavital routes using a dedicated infusion set. It is used to supply higher pressures than those provided by manually clamped gravity infusion sets or infusion controllers. The device has a typical flow range of 1 to 999 ml/hour and delivers solutions from a standard infusion bag or bottle of fluid. It typically has internal batteries that enable operation for a short period when no mains electricity is available (e.g. during transportation 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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	GP Plus (all variants)	- *Medical Device Directive 93/42/EEC* - *EMC Directive 2014/30/EU* - *RoHS2 Directive 2011/65/EU* - *Machinery Directive 2014/53/EU* - *Waste electrical and electronic equipment 2002/96/EC* - *Product Liability 85/374/EEC* - *REACH 2006/121/EC* - *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* - *IEC 62366:2007* - *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 60529:1991+A1:2000* - *EN 1789:2007 +A1:2010* - *ISTA-1A-2014*
	neXus GP	- *Medical Device Directive 93/42/EEC* - *EMC Directive 2014/30/EU* - *RoHS2 Directive 2011/65/EU* - *Machinery Directive 2006/42/EC* - *Waste Electrical and Electronic Equipment 2012/19/EU* - *Product Liability 85/374/EEC* - *REACH 1272/2008* - *Packaging and Packaging Waste Directive 2015/720* - *Battery 2006/66/EC* - *Electronic Instructions for Use of Medical Devices 207/2012* - *Radio Equipment Directive 2014/53/EU* - *EN ISO 13485:2016* - *EN ISO 14971:2012* - *EN ISO 15223-1:2016* - *EN 1041:2008+A1:2013* - *IEC 60601-1:2005+A1:2012* - *IEC 60601-1-2:2014* - *IEC 60601-1-6:2010+A1:2013* - *IEC 62366-1:2015* - *IEC 60601-1-8:2006+A1:2012* - *IEC 60601-2-24:2012* - *IEC 62304:2006+A1:2015* - *EN 60529:1992+A2:2013* - *EN 1789:2007+A2:2014* - *ISTA-2A-2011* - *ETSI EN 300 328 V2.1.1 (2016-11)* - *ETSI EN 301 893 V2.1.1 (2017-05)* - *ETSI EN 301 489-17 V3.1.1 (2016-11)*

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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: 004

Issue Level: 16

Signed:

Giuseppe Tomasini

Date: November 7th, 2019.

Regulatory Affairs Director
MMS - OUS Infusion Pumps

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Product Schedule
Alaris™ GP Volumetric Pump

GMDN Number: 13215

Part Number	Description	EC Product Class
9002TIG03	Alaris™ GP Volumetric Pump with Plus software	IIb
9002TIG03-G	Alaris™ GP Guardrails™ Volumetric Pump with Plus software	IIb
GPneXus1	BD Alaris™ neXus GP	IIb

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