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™ CC 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:	*neXus CC (all variants)*	- *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 2012/19/EU* - *Product Liability 85/374/EEC* - *Packaging and Packaging Waste Directive 94/62/EC* - *Battery Regulation 2023/1542* - *Electronic Instructions for Use of Medical Devices 207/2012* - *Radio Equipment Directive 2014/53/EU* - *EN ISO 13485:2016* - *EN ISO 14971:2019* - *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* - *ISTA-2A-2011* - *ETSI EN 300 328 V2.2.2 (2019-07)* - *ETSI EN 301 893 V2.1.1 (2017-05)* - *ETSI EN 301 489-17 V3.2.4 (2020-09)* - *ETSI EN 301 489-1:V2.2.3 (2019-11)* - *EN 62311:2008* - *Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers AIM 7351731* - *FCC CFR 47 Part 15B*
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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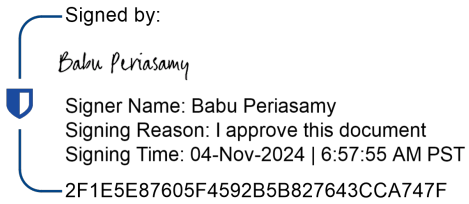
STED File: 008

Issue Level: 38

Signed:

Babu Periasamy



Date:

Senior Director, Regulatory Affairs - WWIPD

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Product Schedule
Alaris™ CC Syringe Pump

GMDN Number: 13217

Part Number	Description	EC Product Class
CCneXus1	BD Alaris™ neXus CC Syringe Pump	IIb
CCneXus1-S	BD Alaris™ neXus CC Syringe Pump	IIb

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Last serial numbers to the EOS SKUs

SKU	SKU Description	Last SN no.	Last manufacturing date
8003TIG03	Alaris™ CC Syringe Pump with Plus Software	302055428	20-Jul-2020
8003TIG03-G	Alaris™ CC Guardrails™ Syringe Pump with Plus Software	372139109	10-May-2024

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