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 Services RO S.R.L Eugeniu Carada Street, no 2–4, Oradea, 410610, Bihor, Romania
Device Description/Family:	Alaris™ PK 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.

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

Applied Standards and Directives:	BD Alaris™ neXus PK Syringe Pump	- 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 - 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+A1:2015+A2:2020 - IEC 60601-1-8:2006+A1:2012 - IEC 60601-2-24:2012 - IEC 62304:2006+A1:2015 - EN 60529:1992+A2:2013 - IEC 60601-2-2:2017 - 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) - FCC CFR 47 Part 15B - EN 62311:2020
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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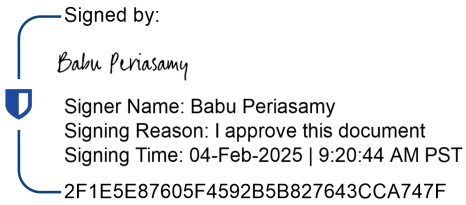
STED File: TF034

Issue Level: 50

Signed:



Babu Periasamy

Date: 04-Feb-2025

Senior Director, Regulatory Affairs - WWIPD

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Product Schedule
Alaris™ PK Syringe Pump

GMDN Number: 13217

Part Number	Description	EC Product Class
PKneXus1	BD Alaris™ neXus PK Syringe Pump	IIb

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

Last serial number to the EOS SKU

SKU	SKU Description	Last SN no.	Last manufacturing date
8005TIG03	Alaris™ PK Plus Syringe Pump	502139502	16-May-2024

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