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, Eysins, CH-1262, Switzerland
EU Representative	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Manufacturing Site (s):	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:	MaxZero™ Needleless Connectors *(See attached Product Schedule)*
EC Product Classification:	Class IIa, Annex IX, Rule 2
GMDN:	*42727 – Positive-pressure needleless valve-connector* *A small, stand-alone, Luer-activated needleless plastic valve intended to mate two related intravenous (IV) line devices [e.g., hypodermic syringe and catheter port or tubing from an IV administration set] and hold them in a secured, sealed, locked position until disconnection, at which point positive pressure from the device causes a small volume of fluid to be expelled from the catheter/tubing. It is intended to eliminate the use of needles for IV administration of medications. This is a single-use device.*

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

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	BS EN ISO 10993-1:2020 BS EN ISO 10993-4:2017 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2023 BS EN ISO 10993-11:2018 BS EN ISO 10993-12:2021 BS EN ISO 10993-16:2017 BS EN ISO 10993-17:2009 ISO 10993-18:2020/Amd 1:2022 BS EN ISO 11137-1:2015+A2:2019 ISO 11137-2:2013/Amd1:2022 BS EN ISO 11607-1:2020+A11:2022 BS EN ISO 11607-2:2020+A11:2022 BS EN ISO 11737-1:2018+A1:2021 BS EN ISO 11737-2:2020 BS EN ISO 13485:2016+A11:2021 BS EN ISO 14644-1:2015 BS EN ISO 14644-2:2015 BS EN ISO 14644-5:2004 BS EN ISO 14971:2019+A11:2021 BS EN ISO 15223-1: 2016/AC:2017 BS EN 20594-1:1994 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: 307

Signed:

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Signer Name: Roya Borazjani
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Roya Borazjani

VP, Regulatory Affairs and Compliance
WW Infusion Preparation and Delivery

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Product Schedule
Needleless Connectors

GMDN Number: 42727

Part Number	Description	EC Product Class
MZ1000	BD MaxZero™ Needleless Connector	II a
MZ1000-BR	BD MaxZero™ Needleless Connector (Brazil specific variant)	II a

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