

## EC DECLARATION OF CONFORMITY

<b>Legal Manufacturer:</b>	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070, USA
<b>Authorised Representative:</b>	Becton Dickinson Distribution Center NV Laagstraat 57, B-9140 Temse, Belgium
<b>Manufacturing Site(s):</b>	Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore
<b>Products:</b>	682245 BD Arterial Cannula
<b>Classification:</b>	Class IIa under Rule 7 of the Council Directive 93/42/EEC, as amended
<b>Conformity Assessment Route:</b>	Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4
<b>GMDN Information:</b>	GMDN Code: 64575 GMDN Term: Peripheral artery cannula GMDN Definition: A short, thin tube intended for short-term ( $\leq 30$ days) percutaneous access to a peripheral artery for invasive blood pressure monitoring and arterial blood sampling; it may in addition be intended for peripheral IV and/or subcutaneous administration of fluid/medication. Also referred to as a peripheral arterial catheter, it is used with an external blood pressure transducer (not included) to enable pressures to be measured; it does not include electronic sensors and is not intended for thermal dilution techniques. It may include devices dedicated to introduction/function (e.g., introducer needle, guidewire, adaptor). This is a single-use device.

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

<b>Harmonised Standards:</b>	EN ISO 14971:2012 (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 13485:2016 (ISO 13485:2016) EN ISO 10555-1:2009 (ISO 10555-1:2013) EN 20594-1:1993 (ISO 594-1:1986) EN ISO 10993-1:2009 (ISO 10993-1:2009) EN ISO 11737-1:2006 (ISO 11737-1:2006) EN ISO 11135-1:2007 (ISO 11135:2014) EN ISO 10993-7:2008 (ISO 10993-7:2008) EN 1041:2008 EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03) EN ISO 14155:2011 (ISO 14155:2011)
<b>Non-Harmonised Standards:</b>	N/A

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<b>Notified Body:</b>	BSI Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Notified Body Number: 2797
<b>EC Certificate Number:</b>	CE 01738
<b>Date of issuance of the original CE certificate:</b>	03 October 1997

Date: 03/31/2021



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VP, Regulatory Affairs  
Becton Dickinson Infusion Therapy Systems Inc.

**VERSION HISTORY****Current Version Prepared By:** Jeremy Kuyakana

<b>Version</b>	<b>Version Description</b>
E	Corrected Legal Manufacturer name. Updated GMDN Code from 10689 to 64575 as well as the GMDN Term and Definition (PCC-2021-00081).
D	CE 01738 renewed (expiration date: 26-May-2024). <u>Header:</u> document changed from TF000008-DEC (SG) to TF000008-DEC.
C	Version cancelled.