

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070, USA
Authorised Representative:	Becton Dickinson Distribution Center NV Laagstraat 57, B-9140 Temse, Belgium
Manufacturing Site(s):	Becton Dickinson Medical (S) Pte Ltd 30 Tuas Avenue 2 Singapore 639461 Singapore
Products:	682245 BD Arterial Cannula
Classification:	Class IIa under Rule 7 of the Council Directive 93/42/EEC, as amended
Conformity Assessment Route:	Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4
GMDN Information:	GMDN Code: 64575 GMDN Term: Peripheral artery cannula GMDN Definition: A short, thin tube intended for short-term (≤ 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.

Harmonised Standards:	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)
Non-Harmonised Standards:	N/A

Document: TF000008-DEC

Version: E

TITLE: Declaration of Conformity for BD Arterial Cannula

Page 2 of 3

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

Date: 03/31/2021



Roya Borazjani
VP, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Inc.

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

Version	Version Description
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.