EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy 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 Becton Dickinson Industrias Cirurgicas Ltda. Avenida Juscelino Kubitschek, 273 Francisco Bernardino - Juiz de Fora - MG / Brazil, 36081-000 Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales Sonora, C.P.84048, Mexico
Products:	381112 BD Angiocath™ IV Catheter 24GA 0.75IN 381123 BD Angiocath™ IV Catheter 22GA 1.00IN 381134 BD Angiocath™ IV Catheter 20GA 1.16IN 381137 BD Angiocath™ IV Catheter 20GA 1.88IN 381144 BD Angiocath™ IV Catheter 18GA 1.16IN 381147 BD Angiocath™ IV Catheter 18GA 1.88IN 381154 BD Angiocath™ IV Catheter 16GA 1.16IN 381157 BD Angiocath™ IV Catheter 16GA 1.88IN 381164 BD Angiocath™ IV Catheter 14GA 1.16IN 381167 BD Angiocath™ IV Catheter 14GA 1.88IN 382258 BD Angiocath™ IV Catheter for Special Placement 16 GA x 3.25 IN 382259 BD Angiocath™ IV Catheter for Special Placement 16 GA x 5.25 IN 382268 BD Angiocath™ IV Catheter for Special Placement 14 GA x 3.25 IN 382269 BD Angiocath™ IV Catheter for Special Placement 14 GA x 5.25 IN 382277 BD Angiocath™ IV Catheter for Special Placement 12 GA x 3.00 IN 382287 BD Angiocath™ IV Catheter for Special Placement 10 GA x 3.00 IN 382412 BD Angiocath Plus™ I.V. Catheter 24GA x 0.75IN 382423 BD Angiocath Plus™ I.V. Catheter 22GA x 1.00IN 382434 BD Angiocath Plus™ I.V. Catheter 20GA x 1.16IN 382437 BD Angiocath Plus™ I.V. Catheter 20GA x 1.88IN 382444 BD Angiocath Plus™ I.V. Catheter 18GA x 1.16IN 382447 BD Angiocath Plus™ I.V. Catheter 18GA x 1.88IN 382457 BD Angiocath Plus™ I.V. Catheter 16GA x 1.77IN 381211 BD Insyte-N™ IV Catheter 24GA 0.56IN 381212 BD Insyte™ IV Catheter 24GA 0.75IN 381223 BD Insyte™ IV Catheter 22GA 1.00IN 381233 BD Insyte™ IV Catheter 20GA 1.00IN

	381234 BD Insyte™ IV Catheter 20GA 1.16IN 381237 BD Insyte™ IV Catheter 20GA 1.88IN 381244 BD Insyte™ IV Catheter 18GA 1.16IN 381247 BD Insyte™ IV Catheter 18GA 1.88IN 381254 BD Insyte™ IV Catheter 16GA 1.16IN 381257 BD Insyte™ IV Catheter 16GA 1.77IN 381267 BD Insyte™ IV Catheter 14GA 1.75IN 381311 BD Insyte-N™ IV Catheter with Wings 24GA 0.56IN 381312 BD Insyte-W™ IV Catheter with Wings 24GA 0.75IN 381323 BD Insyte-W™ IV Catheter with Wings 22GA 1.00IN 381333 BD Insyte-W™ IV Catheter with Wings 20GA 1.00IN 381334 BD Insyte-W™ IV Catheter with Wings 20GA 1.16IN 381337 BD Insyte-W™ IV Catheter with Wings 20GA 1.88IN 381344 BD Insyte-W™ IV Catheter with Wings 18GA 1.16IN 381347 BD Insyte-W™ IV Catheter with Wings 18GA 1.88IN 381354 BD Insyte-W™ IV Catheter with Wings 16GA 1.16IN 381357 BD Insyte-W™ IV Catheter with Wings 16GA 1.77IN
Classification:	Class IIa under Rule 7 of Annex IX 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:	GMDN Code: 64574 GMDN Term: Peripheral intravenous cannula GMDN Definition: A short, thin tube intended to be inserted into a peripheral vein (typically on the hand/arm) to enable short-term (< 30 days) intravenous (IV) access for administration of fluids/medication and blood sampling. Also referred to as a peripheral IV catheter, it is typically assembled with a dedicated introduction needle, and usually includes connectors, injection ports, and wings for fixation. It is not intended to be advanced to the central vasculature. 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 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 20594-1:1993 (ISO 594-1:1986) EN ISO 10555-1:2009 (ISO 10555-1:2013), except Section 4.4 (visible drops) (Angiocath only) EN ISO 10993-1:2009 (ISO 10993-1:2009) EN ISO 10993-7:2008 (ISO 10993-7:2008) EN ISO 11607-1:2009 (ISO 11607-1:2006) EN ISO 11607-2:2006 (ISO 11607-2:2006)

	EN ISO 11135-1:2007 (ISO 11135-1:2007) EN 556-1:2001 EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03) EN 1041:2008
Non-Harmonised Standards:	ISO 594-2:1998 ISO 10555-5:2013
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 original CE certificate:	03 October 1997

Date: 2020-08-07

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

VERSION HISTORY

Current Version Prepared By: Samar Omar

Version	Version Description
I	CE 01738 renewed (expiration date: 26-May-2024). Header: updated product names to full tradename. Legal Manufacturer: corrected address zip code.
H	GMDN: Updated GMDN code, term, and definition with replacement GMDN code 64574.
G	Products: removed “mm” units. Harmonised Standards: updated ISO 13485 revision to 2016 to align with Legal Manufacturer, Authorised Representative, and Manufacturing Sites’ ISO 13485 certifications. Throughout: minor formatting changes.