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 Infusion Therapy Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales Sonora, C.P.84048, Mexico
Products:	383312 BD Saf-T-Intima™ Safety System with Removable PRN (24 GA 0.75 IN) 383313 BD Saf-T-Intima™ Safety System with Y Adapter (24 GA 0.75 IN) 383318 BD Saf-T-Intima™ Safety System with Removable PRN (24 GA 0.75 IN) 383319 BD Saf-T-Intima™ Safety System with Y Adapter (24 GA 0.75 IN) 383322 BD Saf-T-Intima™ Safety System with Removable PRN (22 GA 0.75 IN) 383323 BD Saf-T-Intima™ Safety System with Y Adapter (22 GA 0.75 IN) 383328 BD Saf-T-Intima™ Safety System with Removable PRN (22 GA 0.75 IN) 383329 BD Saf-T-Intima™ Safety System with Y Adapter (22 GA 0.75 IN) 383335 BD Saf-T-Intima™ Safety System with Removable PRN (20 GA 1.00 IN) 383336 BD Saf-T-Intima™ Safety System with Y Adapter (20 GA 1.00 IN) 383338 BD Saf-T-Intima™ Safety System with Removable PRN (20 GA 1.00 IN) 383339 BD Saf-T-Intima™ Safety System with Y Adapter (20 GA 1.00 IN) 383346 BD Saf-T-Intima™ Safety System with Y Adapter (18 GA 1.00 IN) 383348 BD Saf-T-Intima™ Safety System with Y Adapter (18 GA 1.00 IN)
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 Information:	REF 383312, 383313, 383322, 383323, 383335, 383336, 383346, 383338, 383339, 383348 GMDN Code: 40601 GMDN Term: Peripheral vascular catheter GMDN Definition: A sterile, thin, flexible tube inserted into a peripheral artery or vein of a patient to permit short-term (< 30 days) intravascular access for therapeutic treatment or procedures. It typically includes connectors (e.g., Luer hubs) and possibly accessories (e.g., a stylet) to facilitate its placement. It allows for repeated access to the vascular system for less than 30 days and may be used for blood sampling, monitoring of blood pressure, to administer medications (antibiotics), chemotherapeutic agents, nutrients, parenteral solutions, and/or for the injection of contrast media. This is a single-use device. REF 383318, 383319, 383328, 383329 GMDN Code: 61650 GMDN Term: Peripheral vascular/ subcutaneous catheter

	GMDN Definition: A sterile, dual-purpose, thin, flexible tube intended for: 1) insertion into the peripheral vasculature to enable short-term (< 30 days) intravascular access for blood sampling, blood pressure monitoring, fluid/medication administration and/or contrast media injection; and 2) administration of fluids/medication into subcutaneous tissue. It typically includes dedicated accessories to facilitate catheter introduction/function (e.g., connectors, injection ports, stylet, fixation wings, introduction needle). 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 13485:2012 (ISO 13485:2003) EN 20594-1:1993 (ISO 594-1:1986) EN ISO 10555-1:2009 (ISO 10555-1:1995) 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 11135-1:2014) EN 556-1:2001 EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03) EN 1041:2008 EN 15986:2011
Non-Harmonised Standards:	ISO 594-2:1998 ISO 10555-5:2013
Notified Body:	BSI Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP United Kingdom Notified Body Number: 0086
EC Certificate Number:	CE 01738
Date of issuance of the original CE certificate:	03 October 1997

Date: 17 July 2018

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Becton Dickinson Infusion Therapy Systems Inc.

VERSION HISTORY

Current Version Prepared By: Kimberly Geisler

Version	Version Description
D	Header: Enlarged logo; updated format; removed document type; changed "Document Number" to "Document". Body: Removed letterhead address and logo; corrected classification rule and updated description to align with TFCE-07; updated Conformity Assessment Route description to align with CE 01738; changed "List of Harmonised Standards" to "Harmonised Standards"; changed "Other Standards" to "Non-Harmonised Standards"; updated Iso 14971 revision information; removed "EN 980:2008"; moved "ISO 15223-1" to "Harmonised Standards" section and updated version; added version to ISO 10555-5. Corrected NB address (Knowlhill). Throughout: formatting changes.
C	Revised to meet MED-RA-001C requirements.
B	Changed "ISO 13845:2003" to "EN ISO 13485:2012." Added non-DEHP catalog numbers 383318, 383319, 383328, 383329, 383338, 383339, 383348. Note: Catalog numbers 383318, 383319, 383328, 383329 are indicated for subcutaneous infusion in addition to vascular access. Migrated Documents from QDMS to SAP 6.0, changed from numerical to alpha.