

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. 9450 South State Street Sandy, Utah 84070 USA Becton Dickinson Infusion Therapy Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales Sonora, C.P.84048, Mexico
Products:	385100 BD Q-Syte™ Luer Access Split Septum 0.16 ml 385101 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore 385102 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore 385103 BD Q-Syte™ Luer Access Split Septum 0.16 ml (India only) 385104 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore (India only) 385105 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore (India only) 385106 BD Q-Syte™ Vial Access Adapter 0.16 ml (India only) 385108 BD Q-Syte™ Vial Access Adapter 0.16 ml 385150 BD Q-Syte™ Extension Set 15 cm (6IN) 0.60 ml BD Rightbore™-18 385151 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.25 ml 385152 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.00 ml 385153 BD Q-Syte™ Extension Set 36 cm (14 IN) 0.55 ml 385155 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml (India only) 385156 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 2.25 ml (India only) 385157 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 0.45 ml (India only) 385158 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml (India only) 385161 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml 385162 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 2.25 ml 385163 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 0.45 ml 385164 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml 385165 BD Q-Syte™ “Y” Extension Set 20 cm (8 IN) 1.40 ml 385166 BD Q-Syte™ Dual “Y” Extension Set 50 cm (20 IN) 3.20 ml
Classification:	Class IIa under Rule 2 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:	<p><u>REF 385100, 385103</u> GMDN Code: 42743 GMDN Term: Negative-pressure needleless valve-connector GMDN Definition: A small, sterile, 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 negative pressure from the device causes a small volume of retrograde fluid flow into the catheter/tubing. It is intended to eliminate the use of needles for IV administration of medications. This is a single-use device.</p> <p><u>REF 385108, 385106</u> GMDN Code: 58510 GMDN Term: Vial transfer spike GMDN Definition: A sterile device designed to be securely attached to the septum end of a vial to create a channel, by spiking through the vial's sealed stopper, to allow access to the contents of the vial. This device is intended to reduce risk of unwanted exposure to the vial's contents (e.g., liquid medication) by providing a sterile pathway between the vial and a recipient receptacle/device for subsequent delivery to a patient. It typically consists of polyvinyl chloride (PVC) screw cap with an internal spike and an external connector. This is a single-use device.</p> <p><u>REF 385101, 385102, 385104, 385105, 385150, 385151, 385152, 385153, 385155, 385156, 385157, 385158, 385161, 385162, 385163, 385164, 385165, 385166</u> GMDN Code: 12170 GMDN Term: Intravenous administration tubing extension set GMDN Definition: A collection of tubing and connectors intended to establish an extension of tubing where the standard length of the tubing in an intravenous (IV) administration set is insufficient. This is a single-use device.</p>
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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:	<p>EN ISO 14971:2012 (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 13485:2016 (ISO 13485:2016) 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 EN 15986:2011</p>
Non-Harmonised Standards:	<p>ISO 594-2:1998</p>

Document: DC-005

Version: K

TITLE: Declaration of Conformity for BD Q-Syte Devices

Page 3 of 4

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: 13 June 2019



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VERSION HISTORY

Current Version Prepared By: Kimberly Geisler

Version	Version Description
K	<u>Harmonised Standards</u> : updated ISO 13485 revision to 2016 to align with Legal Manufacturer, Authorised Representative, and Manufacturing Sites' ISO 13485 certifications. <u>Throughout</u> : minor formatting changes.
J	<u>Notified Body</u> : Updated BSI address and Notified Body number per CE Certificate No. CE 01738, issued 2019-03-13.
I	<u>Header</u> : Enlarged logo; updated header format; removed document type; changed "Document Number" to "Document". <u>Body</u> : Removed letterhead address and logo; updated Classification and Conformity Assessment Route descriptions to align with TFCE-029 and CE 01738; changed GMDN Code 42631 to 42743 due to GMDN Code 42631 obsolescence; changed "List of Harmonised Standards" to "Harmonised Standards"; changed "Other Standards" to "Non-Harmonised Standards" to align with MED-RA-001C; removed EN 20594-1 to align with PPS-131; removed "EN 980:2008" as it is no longer a harmonized standard; updated ISO 14971 version information; moved "ISO 15223-1" to Harmonised Standards section and updated version; corrected NB address (Knowlhill). <u>Version History</u> : Changed "Ver." to "Version". <u>Throughout</u> : formatting changes.