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 385103 BD Q-Syte™ Luer Access Split Septum 0.16 ml (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 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
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:	REF 385100, 385103 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. REF 385108, 385106 GMDN Code: 43324 GMDN Term: Fluid transfer set, general-purpose. GMDN Definition: A collection of devices and supplies designed to transfer several types of medical fluids (e.g., drugs, vaccines, blood, and solutions) between a first container(s) [e.g., a vial(s) and a second container [e.g., an intravenous (IV) bag]; it is not dedicated to a particular type of fluid or clinical procedure. It is available in a variety of configurations and typically includes tubes, connectors, spike(s), syringes, and caps. This is a single-use device. REF 385101,385150,385151, 385155, 385156, 385157, 385158, 385161, 385162, 385163, 385164, 385165 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.

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.

Applicable Standards:	BS EN ISO 14971:2019 +A11:2021(ISO 14971:2019) BS EN ISO 13485:2016 +A11:2021 (ISO 13485:2016) BS EN ISO 10993-1:2020 (ISO 10993-1:2018) BS EN ISO 10993-7:2008 (ISO 10993-7:2008) BS EN ISO 11607-1:2020/A11:2022 (ISO 11607-1:2019) BS EN ISO 11607-2:2020/A11:2022 (ISO 11607-2:2019) BS EN ISO 11135:2014+A1:2019 (ISO 11135:2014+A1:2018) BS EN 556-1:2001 BS EN ISO 15223-1:2016 (ISO 15223-1:2016) BS EN 1041:2008 ISO 594-2:1998
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: 18-Oct-2024

Signed by:
Darla Harper
Signer Name: Darla Harper
Signing Reason: I approve this document
Signing Time: 18-Oct-2024 | 1:19:12 PM EDT
4ACCBD219ACF4C19A43656348DF6E0CA

Darla Harper, Director of Regulatory Affairs,
WWIPD Consumables

VERSION HISTORY **Current Version Prepared By:** Jo Larden	
Version	**Version Description**
T	Updated in line with update to TFCE-29 – Rev. AB
S	Removal of 385152 as CE mark removed under CC-2022-995 / 500000351262. Removed 385153 as discontinued under MDS-2019-0244 500000249471 / 500000272813
R	Removal of 385102 as CE mark removed under CC-2023-607 Removal of 385104 as End of Life under ECO 500000341464 Removal of 385105 as End of Life under CC-2022-995 Update GMDN 58510 to 43324, applicable to 385106 and 385108, as 58510 no longer active. Update to Standards; Removed BS EN 15986 as no longer applicable as SKU's 385102 and 385105 are no longer CE marked.
Q	Updated in line with update to TFCE-29 – Rev. Y
P	Removal of 385166 as End of Life. Update to Standards; BS EN ISO 11607-1:2009 to ISO 11607-1:2019 / BS EN ISO 11607-1:2020 as per Gap Assessment I20-GAP-006 and included A11:2022 (No impact since the amendment includes informative annexes only) BS EN ISO 11607-2:2006 to ISO 11607-2 :2019 / BS EN ISO 11607-2:2020 as per Gap Assessment I20-GAP-020 and included A11:2022 (No impact since the amendment includes informative annexes only)
O	Technical File updated to update Labels and Boxes with new ANZ Sponsor address and Swiss AR updates. TFCE-29 - Rev. W Update to standards; BS EN ISO 13485:2016 to include A11:2021 further to Gap Assessment I21-REV-008.
N	Update to standards; 1. EN ISO 14971:2012 (ISO 14971:2007) is updated to current version. I20-GAP-009 supports change from ISO 2007 to ISO 2019. I21-GAP-027 supports equivalence of BS EN ISO 14971:2019 +A11:2021 to ISO 14971:2019. 2. EN ISO 10993-1:2009 is updated to current revision. I21-GAP-024 supports change from ISO 2009 to ISO 2018 I21-GAP-024 supports equivalence of BS EN ISO 10993-1: 2020 to ISO 10993-1:2018

	3. EN ISO 11135-1:2007 is updated to current revision. I20-GAP-004 supports change from ISO 2007 to ISO 2014. S19-GAP-020 supports change from ISO 2014 to ISO11135:2014+A1:2018 I21-GAP-012 support equivalence of BS EN ISO 11135:2014+A1:2019 to ISO 11135:2014+A1:2018 4. Updated standards to the BS EN version, where applicable.
M	Updated in line with update to TFCE-29 – Rev. U
L	CE 01738 renewed (expiration date: 26-May-2024).
K	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.
J	Notified Body: Updated BSI address and Notified Body number per CE Certificate No. CE 01738, issued 2019-03-13.