EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Manufacturing Site(s):	Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA Becton, Dickinson and Company (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070 USA
Products:	**367323** - BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12" **367324** - BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12" **367326** - BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12" **367335** - BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 7" **367336** - BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 7" **367338** - BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 7"

	367341 - BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12" **367342** - BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12" **367344** - BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12" **367363** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 25G x 3/4" x 12" **367364** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 23G x 3/4" x 12" **367365** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G x 3/4" x 12" **367391** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 25G x 3/4" x 7" **367392** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 23G x 3/4" x 7" **367393** - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G x 3/4" x 7"
Classification:	EU Class IIa medical device as defined in the Medical Device Directive (93/42/EEC), Annex IX, Section 2.3, Rule 7 - all surgically invasive devices intended for short term use, to which the exceptions do not apply. Canada Class II per Canadian Medical Devices Regulations, Schedule 1 of SOR/98-282 - All surgically invasive devices are classified as Class II to which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 58497 GMDN Term: Blood collection set, invasive

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.

Standards – (Harmonized)	EN 556-1:2001 EN 1041:2013 EN ISO 10993 - Series EN ISO 13485:2016 EN 1707:1997 EN ISO 14971:2019 EN ISO 11607-1:2010 EN ISO 11137-1:2015 AMD 2019 EN ISO 11137-2:2015 EN ISO 11137-3:2017 EN 62366-1 Edition 1.1 2020-06 EN ISO 15223-1:2016
Standards – (Non- Harmonized)	ASTM D999:2008 ASTM D5276-1998 ASTM D-4169:2014 ISO 11737-1:2018 AMD 2021
Notified Body:	National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
CE Certificate Number:	252.191
Date of issuance of original CE certificate:	27 April 1997

Date: 06-Dec-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 06-Dec-2022 | 10:16:05 PM GMT
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Anne Zavertnik
Vice President, Regulatory Affairs
Integrated Diagnsotic Systems

REVISION HISTORY

Current Version Prepared By: Victor Uzochukwu

REV.	Revision Description	Releasing ECO (if applicable)
01	Release the Declaration of Conformity for BD Vacutainer® Push Button Blood Collection Sets.	ECO 191873
02	Corrected address error, correction of zipcode.	N/A
03	Revised to include the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set line extension. Corrected name of European Representative. Corrected name of Notified Body to Association frin Authority..	N/A
04	Corrected typo for catalog 367365 length from 7' to 12'. Corrected document number from VTF0030-03 to VTF0030-02.	N/A
05	Put document in correct template - MED-RA-001C Rev. 02. Added Harmonized and Non-Harmonized Standards Sections. Changed authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 10-Dec-2018
06	Added Plymouth as an additional manufacturing site.	N/A 18-Jan-2019
07	Changed Authorized Rep to BD Switzerland Sarl; removed reference to standard EN ISO 11135-2014 as it is not relevant for this product; changed authorized signature to Kay Taylor	N/A August 2019
08	Update sterilization standards EN ISO 11137-3: 2017 per BDVS-2020-04-29-112801 and EN ISO 11737-1:2018 per BDVS-2020-04-29-085157; updated header to IDS, Specimen Management.	N/A June 2020
09	Updated GMDN code and term to 58284 due to obsoletion of 58490.	N/A December 2021
10	Updated GMDN code to 58497 and associated GMDN term per 252.191.36. Updated EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019. per BDVS-2021-12-17-102739 Removed EN from EN ISO 11737-1:2018 to align with other VTF0030 documentation. Updated ISO 11737-1:2018 to ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739	N/A January 2022
11	Moved ISO 11737-1:2018 AMD 2021 to the non-harmonized standard section.	N/A January 2022
12	Modified European Authorized Representative from BD Switzerland to BD Ireland. Change to the EU Authorized	N/A May 2022

	Representative name and address due to dissolution of the Swiss-EU mutual recognition agreement. NSAI Regulatory Statement Letter accepting the appointment of BD Ireland as the EAR, dated 24 Feb 2022. Corrected references to EN ISO 14971:2012 to the current standard EN ISO 14971:2019.	
13	Updated Authorized Representative: Becton Dickinson Ireland. to Becton Dickinson Ireland Limited	N/A Nov 2022