EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	BD Switzerland Sárl Terre Bonne Park – A4 Route de Crassier 17 1262 Eysins Switzerland
Manufacturing Site(s):	Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA
Products:	**367354** - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4" x 7" tubing **367355** - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4" x 7" tubing **367356** - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 25G x 3/4" x 12" tubing **368657** - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4" x 12" tubing **368658** - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4" x 12" tubing **368684 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4" x 7" tubing **368685 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 "x 7" tubing **368686 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,21G x 3/4 "x 7" tubing **368687-** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4 "x.,12" tubing **368688 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 "x 12" tubing **368689 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,21G x 3/4" x 12" tubing

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 1041:2008+ A1:2013 EN ISO 10993 - Series EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 11607-1:2009 EN ISO 11137-1:2015 AMD 2019 EN ISO 11137-2:2015 EN ISO 11737-2:2020 EN ISO 15223-1:2016
Standards - (Non Harmonized)	EN ISO 11737-1:2018 AMD 2021 EN 62366-1:2015

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:	252.810
Date of issuance of original CE certificate:	20 July 2010

Date: 13-Feb-2022

Anne Zavertnik
VP, Regulatory Affairs
Integrated Diagnostic Solutions

TITLE: Declaration of Conformity for BD Vacutainer® Push Button Blood Collection Set With Pre-Attached Holder

REVISION HISTORY

Current Version Prepared By: A. Kirby

REV.	Revision Description	Releasing ECO (if applicable)
01	Release the Declaration of Conformity for BD Vacutainer® Push Button Blood Collection Sets with Pre-Attached Holder	ECO191904
02	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 11-Dec-2018
03	Changed the Authorized Representative to BD Switzerland Sarl; removed reference to standard EN ISO 11135-2014 as it is not relevant for this product; changed the authorized signature to Kay Taylor.	N/A (August 2019)
04	• Update to a 6 new model number tp the PBBCS-PAH CE Certificate 252.810.05 **368684 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4" x 7" tubing **368685 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 "x 7" tubing **368686 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,21G x 3/4 "x 7" tubing **368687-** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4 "x.,12" tubing **368688 -** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 "x 12" tubing **368689-** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,21G x 3/4" x 12" tubing • Marked EN ISO 11737-1:2018 and EN 62366-1:2015 as non-harmonized standard and update revision. • Add EN ISO 11737-2:2009 and EN -ISO 11137:2:2015, missing • Remove EN 1707:1997 – not applicable – specific for devices with lock fittings. • Correct: EN 1041:2013 to EN 1041:2008+A1:2013 and EN ISO 11607-1:2010 to EN ISO11607-1:2009	N/A 12-Dec-2019
05	• Updated Standards section for: EN ISO 11737-2 – 2019 – updated from 2019 to 2020; updated header updated to IDS, Specimen Management.	N/A June 2020

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REV.	Revision Description	Releasing ECO (if applicable)
06	• Per ACR PAS 2021-0004, removed catalog numbers 367353 and 367356. • Updated responsible person from Kay Taylor to Anne Zavertnik. • Updated GMDN code and term to 58497 due to obsoletion of 58490 per 252.810.08	N/A December 2021
07	Updated EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019, and EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739.	N/A January 2022