

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

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	BD Switzerland Sàrl 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:	<p>367353 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 25G x 3/4” x 7” tubing</p> <p>367354 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4” x 7” tubing</p> <p>367355 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4” x 7” tubing</p> <p>367356 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 25G x 3/4” x 12” tubing</p> <p>368657 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4” x 12” tubing</p> <p>368658 - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4” x 12” tubing</p> <p>368684 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4” x 7” tubing</p> <p>368685 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4” x 7” tubing</p> <p>368686 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4” x 7” tubing</p> <p>368687 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4” x 12” tubing</p> <p>368688 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4” x 12” tubing</p> <p>368689 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4” x 12” tubing</p>

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Classification:	<p>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.</p> <p>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.</p>
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	<p>GMDN Code: 58490 GMDN Term: Blood collection/intravenous fluid administration set</p>

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)	<p>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 EN ISO 11137-2:2015 EN ISO 11737-2:2020 EN ISO 15223-1:2016</p>
Standards- (Non Harmonized)	<p>EN ISO 11737-1:2018 EN 62366-1:2015</p>

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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: 24-June-2020



Kay Taylor
VP, Regulatory Affairs
Life Sciences and IDS

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<u>REVISION HISTORY</u>		
Current Version Prepared By: Sravan Rajamani		
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	<ul style="list-style-type: none"> • Update to a 6 new model number to the PBBCS-PAH CE Certificate 252.810.05 <p>368684 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4" x 7" tubing</p> <p>368685 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4 "x 7" tubing</p> <p>368686 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4 "x 7" tubing</p> <p>368687- BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4 "x., 12" tubing</p> <p>368688 - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4 "x 12" tubing</p> <p>368689- BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 12" tubing</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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