

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

**EC DECLARATION OF CONFORMITY**

<b>Legal Manufacturer:</b>	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
<b>Authorized Representative:</b>	BD Switzerland Sàrl Terre Bonne Park – A4 Route de Crassier 17 1262 Eysins Switzerland
<b>Manufacturing Site(s):</b>	Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA
<b>Products:</b>	<p><b>367353</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 25G x 3/4” x 7” tubing</p> <p><b>367354</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4” x 7” tubing</p> <p><b>367355</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4” x 7” tubing</p> <p><b>367356</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 25G x 3/4” x 12” tubing</p> <p><b>368657</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 21G x 3/4” x 12” tubing</p> <p><b>368658</b> - BD Vacutainer® Push Button Blood Collection Set, With Pre-Attached Holder, 23G x 3/4” x 12” tubing</p> <p><b>368684</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4” x 7” tubing</p> <p><b>368685</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4” x 7” tubing</p> <p><b>368686</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4” x 7” tubing</p> <p><b>368687</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4” x 12” tubing</p> <p><b>368688</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4” x 12” tubing</p> <p><b>368689</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4” x 12” tubing</p>

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<b>Classification:</b>	<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>
<b>Conformity Assessment Route:</b>	Annex II, Medical Device Directive 93/42/EEC
<b>GMDN:</b>	<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.

<b>Standards – (Harmonized)</b>	<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>
<b>Standards- (Non Harmonized)</b>	<p>EN ISO 11737-1:2018 EN 62366-1:2015</p>

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<b>Notified Body:</b>	National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
<b>CE Certificate Number:</b>	252.810
<b>Date of issuance of original CE certificate:</b>	20 July 2010

Date: 24-June-2020

  
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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"> <li>• Update to a 6 new model number to the PBBCS-PAH CE Certificate 252.810.05</li> </ul> <p><b>368684</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4” x 7” tubing</p> <p><b>368685</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 “x 7” tubing</p> <p><b>368686</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,21G x 3/4 “x 7” tubing</p> <p><b>368687</b>- BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,25G x 3/4 “x.,12” tubing</p> <p><b>368688</b> - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder,23G x 3/4 “x 12” tubing</p> <p><b>368689</b>- 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"> <li>• Marked EN ISO 11737-1:2018 and EN 62366-1:2015 as non-harmonized standard and update revision.</li> <li>• Add EN ISO 11737-2:2009 and EN -ISO 11137:2:2015, missing</li> <li>• Remove EN 1707:1997 – not applicable – specific for devices with lock fittings.</li> <li>• Correct: EN 1041:2013 to EN 1041:2008+A1:2013 and EN ISO 11607-1:2010 to EN ISO11607-1:2009</li> </ul>	N/A  12-Dec-2019
05	<ul style="list-style-type: none"> <li>• Updated Standards section for: EN ISO 11737-2 – 2019 – updated from 2019 to 2020; updated header updated to IDS, Specimen Management.</li> </ul>	N/A June 2020