

**TITLE: Declaration of Conformity for BD Vacutainer® Blood Collection Set and Vacutainer® Brand Safety-Lok™ Blood Collection Set**

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**EC DECLARATION OF CONFORMITY**

<b>Legal Manufacturer:</b>	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
<b>Authorised Representative:</b>	Becton, Dickinson and Company (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
<b>Manufacturing Site(s):</b>	<p><b>Manufacturing: BD Vacutainer® Safety-Lok™ Blood Collection Set</b> Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA</p> <p><b>Manufacturing and Sterilization: BD Vacutainer® Blood Collection Set and BD Vacutainer® Safety-Lok™ Blood Collection Set</b> Nipro Medical Industries, Ltd. Tatebayashi Plant 2-19-64 Matsubara, Tatebayashi-shi Gunma, 374-8518 Japan</p> <p>Nipro (Thailand) Corporation Limited 10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayuttaya 13110, Thailand</p>
<b>Products:</b>	<p><b>362093</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾</p> <p><b>362094</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾</p> <p><b>362095</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾</p> <p><b>367246</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾</p> <p><b>367247</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾</p> <p><b>367282</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾</p>

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	<p><b>367284</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx 3/4</p> <p><b>367286</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx 3/4</p> <p><b>367288</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx 3/4</p> <p><b>367295</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p> <p><b>368382</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p> <p><b>368383</b> BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p>
<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: which states that all surgically invasive devices intended for short term use, to which the exceptions do not apply.</p> <p>Canada Class II per Schedule 1, Canadian Medical Device Regulations (CMDR), SOR/98-282 which states that all surgically invasive devices are classified as Class II in 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</p> <p>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>Harmonized Standards:</b>	<p>EN 1041:2013</p> <p>EN ISO 10993 - Series</p> <p>EN ISO 11135:2014</p> <p>EN ISO 13485:2016</p> <p>EN 1707:1997</p> <p>EN-ISO-15223-1:2016</p> <p>EN ISO 11607-1:2010</p> <p>EN ISO 11737-1:2006</p> <p>EN ISO 14971:2012</p> <p>EN ISO 14155:2011</p>
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<b>Non-Harmonized Standards</b>	ASTM D5276-98:1998 ASTM D999:2008 ASTM D-4169:2014
<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>	252-191
<b>Date of issuance of original CE certificate:</b>	27 April 1997

Date: *10 July 2018*



Vernon Brown  
Director Regulatory Affairs  
BD Preanalytical Systems  
Becton, Dickinson and Company (BD)

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**REVISION HISTORY**

Current Version Prepared By: Pamela Sanecki

<b>REV.</b>	<b>Revision Description</b>	<b>Releasing ECO (if applicable)</b>
04	Initial Release of new DoC template which incorporates requirements of MED-RA-001C. Previous revision histories are contained in the DoC up to Rev. 03.	N/A
05	Removed EN980:2008 and revised EN ISO 13485:2012 to EN ISO 13485:2016, revised EN ISO 15223-1:2012 to EN ISO 15223-1:2016 in the Harmonized Standards section.	N/A
06	Updated Standards revision dates to comply with V08-510-01.	N/A
07	Updated to "Becton, Dickinson and Company (BD) to align with our certification.	N/A