

EC DECLARATION OF CONFORMITY

<p>Legal Manufacturer:</p>	<p>Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA</p>
<p>Authorized Representative:</p>	<p>Becton, Dickinson and Company (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK</p>
<p>Manufacturing Site(s):</p>	<p>Manufacturing: BD Vacutainer® Safety-Lok™ Blood Collection Set Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA</p> <p>Manufacturing and Sterilization: BD Vacutainer® Blood Collection Set and BD Vacutainer® Safety-Lok™ Blood Collection Set 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>
<p>Products:</p>	<p>362093 BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾ 362094 BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾ 362095 BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾ 367246 BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾ 367247 BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾ 367282 BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾</p>

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

	<p>367284 BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx 3/4</p> <p>367286 BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx 3/4</p> <p>367288 BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx 3/4</p> <p>367295 BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p> <p>368382 BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p> <p>368383 BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4</p>
Classification:	<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>
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	<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.

Harmonized Standards:	<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>
------------------------------	---

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

Non-Harmonized Standards	ASTM D5276-98:1998 ASTM D999:2008 ASTM D-4169:2014
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: *12-December-2018*



Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

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

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
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
08	Updated authorized approval to Bradford Spring, VP Regulatory Affairs.	N/A 16-Nov-2018