EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorised Representative:	Becton, Dickinson and Company (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Manufacturing Site(s):	**Manufacturing: BD Vacutainer® Safety-Lok™ Blood Collection Set** Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA **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 Nipro (Thailand) Corporation Limited 10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayuttaya 13110, Thailand
Products:	**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

	367284 BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾ **367286** BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾ **367288** BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾ **367295** BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾ **368382** BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾ **368383** BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾
Classification:	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. 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.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 58490 GMDN Term: Blood collection/intravenous fluid administration set

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:	EN 1041:2013 EN ISO 10993 - Series EN ISO 11135:2014 EN ISO 13485:2016 EN 1707:1997 EN-ISO-15223-1:2016 EN ISO 11607-1:2010 EN ISO 11737-1:2006 EN ISO 14971:2012 EN ISO 14155:2011

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: 10 July 2018

Vernon Brown
Director 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