

**TITLE: Declaration of Conformity for
BD Vacutainer® Safety-Lok™ Blood Collection Set
with Pre-Attached Holder**

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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):	Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA Nipro Medical Industries, Ltd. Tatebayashi Plant 2-19-64 Matsubara, Tatebayashi-shi Gunma, 374-8518 Japan *Note- Nipro Medical Industries is approved to manufacture 368654 and 368655 only
Products:	<p>368652 BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 12"</p> <p>368653 BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 12"</p> <p>368654 BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 7"</p> <p>368655 BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 7"</p>

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Classification:	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. 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.
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.

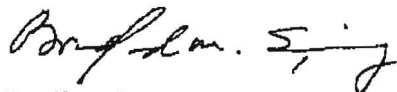
Standards – (Harmonized)	EN 556-1:2001 EN 1041:2013 EN ISO 10993 - Series EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 11607-1:2010 EN ISO 11135:2014 EN ISO 11137-1:2015 EN ISO 11737-1:2006 EN ISO 14155:2011 EN ISO 15223-1:2016 EN 1041:2013
Standards – (Non- Harmonized)	ASTM D999:2008 ASTM D5276-98 ASTM D-4169:2014

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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:	252-191
Date of issuance of original CE certificate:	27 April 1997

Date: August 16, 2018

A handwritten signature in dark ink, appearing to read "Bradford Spring".

Bradford Spring
VP, Regulatory Affairs & Compliance
BD Life Sciences -- Preanalytical Systems
Becton, Dickinson and Company (BD)

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REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Release the Declaration of Conformity for BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder.	N/A
B-02	Under Authorized Representative changed BD Diagnostics, Preanalytical Systems to Becton, Dickinson and Company.	N/A
C-03	Added Nipro Japan to Manufacturing Site(s). Substantial change submitted to NSAI 252.191.27.	N/A
D-04	Removed the change made in Rev. C-03 as the NSAI change submitted has not yet been approved. Included the Standards. Correct template used.	N/A
E-05	Added Nipro Japan to Manufacturing Sites section per ACR PAS 000545-00 and NSAI Approval 252.191.27	N/A