EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
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® 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 Ayutthaya 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: 58497 GMDN Term: Blood collection set, invasive

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 11135:2014EN ISO 13485:2016 EN 1707:1997 EN-ISO-15223-1:2016 EN ISO 11607-1:2010 EN ISO 11737-1:2018 EN ISO 14971:2019 EN ISO 14155:2011

Non-Harmonized Standards	ASTM D5276-98:1998 ASTM D999:2008 ASTM D-4169:2014 ISO 11737-1:2018 AMD 2021
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: 20-Dec-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 20-Dec-2022 | 10:39:45 PM GMT
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Anne Zavertnik
Vice President, Regulatory Affairs
Integrated Diagnostic Solutions

REVISION HISTORY

Current Version Prepared By: Eileen Hiller

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
09	Removed “Blood Collection Sets” from the title as it no longer applies. Changed the Authorized Rep to BD Switzerland Sarl; changed authorized signature to Kay Taylor.	N/A August 2019
10	Update sterilization standard to ISO 11737-1:2018 per BDVS-2020-04-29-085157; updated header to IDS, Specimen Management.	N/A June 2020
11	Update GMDN code to 58497 and GMDN term to align with 58497 code per 252.191.36.	N/A December 2021
12	Corrected GMDN term to align with revised code 58497 per 252.191.36. Added ISO 11737-1:2018 AMD 2021 to non-harmonized standards list per BDVS-2021-12-17-102739	N/A January 2022
13	Updated European Authorized Representative from BD Switzerland to BD Ireland. Change to the EU Authorized Representative name and address due to dissolution of the Swiss-EU mutual recognition agreement. NSAI Regulatory Statement Letter accepting the appointment of BD Ireland as the EAR, dated 24 Feb 2022. Update any references to EN ISO 14971:2012 to: EN ISO 14971:2019 per IDSQUALITYPLAN7591	N/A May 2022
14	Update Nipro Thailand Address, corrected spelling of Ayutthaya, inserted “h” to correct spelling.	N/A July 2022
15	Corrected EU AR information – changed LTD to Limited	N/A December 2022