# EU DECLARATION OF CONFORMITY (DoC)

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| **Manufacturer:** | Becton, Dickinson and Company<br>1 Becton Drive<br>Franklin Lakes, NJ 07417<br>USA |
| **Manufacturer SRN:** | US-MF-000019182 |
| **Authorised Representative:** | Becton Dickinson Ireland Ltd.,<br>Donore Road, Drogheda,<br>Co. Louth, A92 YW26,<br>Ireland |
| **Authorised Representative SRN:** | IE-AR-000007610 |
| **Product:** | BD Vacutainer® Safety-Lok™ Blood Collection Set (see page 2) |
| **Basic UDI-DI:** | 038290SZEOSWRES3 |
| **Risk Class and Rule:** | Class IIa, Rule 7 |
| **Intended Purpose** | **BD Vacutainer® Safety-Lok™ Blood Collection Set**<br>The BD Vacutainer® Safety-Lok™ Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for use in the general population by healthcare professionals experienced in phlebotomy for venipuncture to obtain blood specimens from patients, including those with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male Luer adapter, the device allows the clinician to obtain a blood specimen from the female Luer connector with a syringe, if necessary. The device can be used by healthcare professionals with infusion experience for short-term, single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and is to remain under the direct supervision of a clinician.<br>The safety shield is designed to mitigate the possibility of an accidental needlestick injury if manually activated after use. |
| **Notified Body:** | National Standards Authority of Ireland (NSAI),<br>1 Swift Square,<br>Northwood,<br>Santry, Dublin 9, Ireland<br>Notified Body Number: 0050 |

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

## Conformity Assessment Route:

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| ☒ ANNEX IX Chapter I and III – Quality management System | EC CERTIFICATE No.: 745.056 |
| ☐ ANNEX IX Chapter II - Technical Documentation | EC CERTIFICATE No.: |
| ☐ ANNEX X Type Examination | EC CERTIFICATE No.: |
| ☐ ANNEX XI Part A Production Quality Assurance | EC CERTIFICATE No.: |
| ☐ ANNEX XI Part B Product Verification | EC CERTIFICATE No.: |
| ☒ ANNEX II & III Technical Documentation | N/A |

## Common Specifications (CS):

Common specifications have not been issued for this product.

## Devices Covered by this DoC:

| SKU# | Device Name | Device Class |
|---|---|---|
| 367246 | BD Vacutainer® Safety-Lok™ Blood Collection Set 21G x 3/4" x 12" (0.8 x 19 mm x 305 mm) | Class IIa |
| 367247 | BD Vacutainer® Safety-Lok™ Blood Collection Set 23G x 3/4" x 12" (0.6 x 19 mm x 305 mm) | |
| 367282 | BD Vacutainer® Safety-Lok™ Blood Collection Set 21G x 3/4" x 7" (0.8 x 19 mm x 178 mm) | |
| 367284 | BD Vacutainer® Safety-Lok™ Blood Collection Set 23G x 3/4" x 7" (0.6 x 19 mm x 178 mm) | |
| 367286 | BD Vacutainer® Safety-Lok™ Blood Collection Set 21G x 3/4" x 12" (0.8 x 19 mm x 305 mm) | |
| 367288 | BD Vacutainer® Safety-Lok™ Blood Collection Set 23G x 3/4" x 12" (0.6 x 19 mm x 305 mm) | |
| 367295 | BD Vacutainer® Safety-Lok™ Blood Collection Set 25G x 3/4" x 7" (0.5 x 19 mm x 178 mm) | |
| 368382 | BD Vacutainer® Safety-Lok™ Blood Collection Set 25G x 3/4" x 12" (0.5 x 19 mm x 305 mm) | |
| 368383 | BD Vacutainer® Safety-Lok™ Blood Collection Set 25G x 3/4" x 12" (0.5 x 19 mm x 305 mm) | |

| Authorised Signatory: | |
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| **Name & Title:** | Nathan Carrington, Vice President, Regulatory Affairs |
| **On behalf of:** | Becton, Dickinson and Company |
| **Place of Issue:** | Franklin Lakes, New Jersey, USA. |
| **Date of Issue:** | 25-Jun-2024 |
| **Signature:** | DocuSigned by:<br>Nathan Carrington<br>Signer Name: Nathan Carrington<br>Signing Reason: I approve this document<br>Signing Time: 25-Jun-2024 \| 9:54:42 AM PDT<br>5D0EA9C34D1D4401BADA25407286BEF2 |

## DECLARATION OF CONFORMITY Revision History:

| Version: | Detailed Change Description: |
|---|---|
| 1.0 | Initial Release. New document created to meet Regulation (EU) 2017/745 compliance. |