



Manufacturer's Declaration of Certificate Validity:

with respect to the validity of certificates issued under Council Directive 93/42/EEC on medical devices Directive 93/42/EEC (MDD) on medical devices that have been extended as a result of the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Manufacturer name	Becton, Dickinson and Company
Manufacturer address	1 Becton Drive Franklin Lakes, New Jersey 07417, USA
EUDAMED SRN (if available)	US-MF-000019182

Authorised Representative name (if applicable)	Becton Dickinson Ireland Ltd.
Authorised Representative address	Donore Road, Drogheda Co. Louth, A92 YW26, Ireland
EUDAMED SRN (if available)	IE-AR-000007610

This declaration confirms that the devices listed in the attached schedule meet following conditions for extension of their certificates issued under Council Directive 93/42/EEC (MDD) on medical devices as stated in the regulation 2023/607:

- The certificate(s) covering the listed devices was valid on the 26 May 2021.
- The devices continue to comply with Directive 93/42/EEC (MDD).
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) before the expiry date of the listed certificate.
- Post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.



Signed for and on behalf of the manufacturer:

Signature:

DocuSigned by:

 Signer Name: Anne Zavertnik
 Signing Reason: I approve this document
 Signing Time: 14-Apr-2023 | 6:09:16 PM BST
 DC6A638A32E64A8A91F9D8DE330F0415

Date: 14-Apr-2023

Print name: Anne Zavertnik

Title/position: VP, Regulatory Affairs, Integrated Diagnostic Solutions

Manufacturer name: Becton, Dickinson and Company

Schedule of devices

Model Number/ Catalogue number	Device Name	Certificate number ⁱ	Expiry date on the certificate ⁱⁱ	Extended expiry date ⁱⁱⁱ
367300	BD Vacutainer® Luer Adapter	252.548	May-18-2023	Dec-31-2028
364810	BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter (200 count per carton)	252.548	May-18-2023	Dec-31-2028
36481000	BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter (198 count per carton)	252.548	May-18-2023	Dec-31-2028
364902	BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Multiple Sample Adapter (200 count per case)	252.548	May-18-2023	Dec-31-2028
36490200	BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Multiple Sample Adapter (198 count per case)	252.548	May-18-2023	Dec-31-2028
367338	BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028
367336	BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028
367335	BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028
367344	BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367342	BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367341	BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367326	BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367324	BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367323	BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367393	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028



Model Number/ Catalogue number	Device Name	Certificate number ⁱ	Expiry date on the certificate ⁱⁱ	Extended expiry date ⁱⁱⁱ
367392	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 23G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028
367391	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 25G x 3/4" x 7"	252.191	Jun-18-2023	Dec-31-2028
367365	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 21G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367364	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 23G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367363	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, 25G x 3/4" x 12"	252.191	Jun-18-2023	Dec-31-2028
367354	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 7" tubing	252.810	May-26-2024	Dec-31-2028
367355	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 7" tubing	252.810	May-26-2024	Dec-31-2028
367356	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
368657	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
368658	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
368684	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4" x 7" tubing	252.810	May-26-2024	Dec-31-2028
368685	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 7" tubing	252.810	May-26-2024	Dec-31-2028
368686	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 7" tubing	252.810	May-26-2024	Dec-31-2028
368687	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 25G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
368688	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 23G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
368689	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with Pre-Attached Holder, 21G x 3/4" x 12" tubing	252.810	May-26-2024	Dec-31-2028
362093	BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx 3/4"	252.191	Jun-18-2023	Dec-31-2028
362094	BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx 3/4"	252.191	Jun-18-2023	Dec-31-2028
362095	BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx 3/4"	252.191	Jun-18-2023	Dec-31-2028
367246	BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx 3/4"	252.191	Jun-18-2023	Dec-31-2028

Model Number/ Catalogue number	Device Name	Certificate number ⁱ	Expiry date on the certificate ⁱⁱ	Extended expiry date ⁱⁱⁱ
367247	BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾	252.191	Jun-18-2023	Dec-31-2028
367282	BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾	252.191	Jun-18-2023	Dec-31-2028
367284	BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾	252.191	Jun-18-2023	Dec-31-2028
367286	BD Vacutainer® Safety-Lok™ Blood Collection Set 21Gx ¾	252.191	Jun-18-2023	Dec-31-2028
367288	BD Vacutainer® Safety-Lok™ Blood Collection Set 23Gx ¾	252.191	Jun-18-2023	Dec-31-2028
367295	BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾	252.191	Jun-18-2023	Dec-31-2028
368382	BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾	252.191	Jun-18-2023	Dec-31-2028
368383	BD Vacutainer® Safety-Lok™ Blood Collection Set 25Gx ¾	252.191	Jun-18-2023	Dec-31-2028
368652	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 21G x ¾" x 12"	252.191	Jun-18-2023	Dec-31-2028
368653	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 23G x ¾" x 12"	252.191	Jun-18-2023	Dec-31-2028
368654	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 21G x ¾" x 7"	252.191	Jun-18-2023	Dec-31-2028
368655	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder, 23G x ¾" x 7"	252.191	Jun-18-2023	Dec-31-2028
368609	BD Vacutainer® Eclipse™ Blood Collection Needle, 21G x 1 ¼"	252.190	May-26-2024	Dec-31-2028
368610	BD Vacutainer® Eclipse™ Blood Collection Needle, 22G x 1 ¼"	252.190	May-26-2024	Dec-31-2028
368650	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 21G x 1 ¼"	252.190	May-26-2024	Dec-31-2028
368651	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 22G x 1 ¼"	252.190	May-26-2024	Dec-31-2028
301746	BD Vacutainer® Flashback Blood Collection Needle, 21G x 1", 3.94 (0.8mm x 25mm)	252.190	May-26-2024	Dec-31-2028
301747	BD Vacutainer® Flashback Blood Collection Needle, 22G x 1", 3.94 (0.7mm x 25mm)	252.190	May-26-2024	Dec-31-2028
365077	BD Vacutainer® Flashback Blood Collection Needle, 21G x 1", 3.94 (0.8mm x 25mm) - INDIA	252.190	May-26-2024	Dec-31-2028
365076	BD Vacutainer® Flashback Blood Collection Needle, 22G x 1", 3.94 (0.7mm x 25mm) - INDIA	252.190	May-26-2024	Dec-31-2028

ⁱ Number of certificate issued under Directive 93/42/EEC (MDD)

ⁱⁱ The expiry date on the certificate issued under Directive 93/42/EEC (MDD)

ⁱⁱⁱ Extended expiry date according to Article 120 3b and 3c, Regulation (EU) 2017/745 (MDR).