Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Becton, Dickinson and Company

1 Becton Drive
Franklin Lakes
NJ 07417-1880
USA

to the Product Family

Luer Adapters, Transfer Devices and Access Devices

GMDN Code: 58136, 60579

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.548**
Original Approval:	**19 May 1997**
Last Amended on:	**08 January 2019**
Remains valid until:	**18 May 2023**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

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):	BD Caribe, Ltd. Road 31, KM. 24.3 P.O. Box 4010 Juncos, Puerto Rico 00777-0410
Products:	**364810** BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter (200 count per carton) **364810 00** BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter (198 count per carton)
Classification:	EU Class I Sterile per Annex IX, Rule 1 of the Medical Device Directive (93/42/EEC). Canada Class I per Schedule 1, Part 1, Rule 7, sub-rule 1 of the Canadian Medical Device Regulations (CMDR), SOR//98-282 which states that all other non-invasive devices are classified as Class I in which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 58136 GMDN Term: Syringe, blood collection tube transfer, IVD

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:	EN 556-1 – 2001 EN 1041 – 2013 EN ISO 10993 - Series EN-ISO-15223-1:2016 EN ISO 11135 - 2014 EN ISO 11607-1 – 2010 EN ISO 11737-1 – 2006 EN ISO 13485 – 2016 EN ISO 14971 – 2012 EN ISO 14155 - 2011
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:	252-548
Date of issuance of original CE certificate:	19 May 1997

Date: JANUARY 31, 2019

Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

TITLE: **Declaration of Conformity for BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter**

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Removed San Lorenzo and replaced with Juncos as Manufacturing Site.	N/A
03	Changed GMDN code to 58136 as the old number was obsoleted. In the Standards section, deleted EN-980 and updated the revision date on EN ISO 15223-1-2016.	N/A
04	Updated Standards Rev dates to comply with V08-510-01 Rev. 04; changed authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 16-Nov-2018
05	Added Catalog Number with Variant Code to indicate case count change as per ACR PAS 000650-01.	N/A Feb-2019

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	Becton Dickinson and Company (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Manufacturing Site(s):	**Manufacturing**: BD Caribe, Ltd. Road 31, KM 24.3 Juncos, PR 00777-4010
Products:	**364902** BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Mutiple Sample Adapter (200 count per case) **364902 00** BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Mutiple Sample Adapter (198 count per case)
Classification:	EU Class I Sterile per Annex IX, Rule 1 of the Medical Device Directive (93/42/EEC). Canada Class I per Schedule 1, Part 1, Rule 7, sub-rule 1 of the Canadian Medical Device Regulations (CMDR), SOR//98-282 which states that all other non-invasive devices are classified as Class 1 in which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 60579 GMDN Term: Blood collection luer adapter

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.

TITLE: **Declaration of Conformity for BD Vacutainer® Luer-Lok™ Access Device Holder With Pre-Attached Multiple Sample Adapter**

Standards:	EN 556-1:2001 EN 1041:2013 EN ISO 15223-1:2016 EN ISO 11135:2014 EN ISO 11607-1:2010 EN ISO 11737-1:2006 EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 14155:2011
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:	252-548
Date of issuance of original CE certificate:	19 May 1997

Date: February 5, 2019

Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

TITLE: Declaration of Conformity for
BD Vacutainer® Luer Lok™ Access Device Holder
With Pre-Attached Multiple Sample Adapter

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Removed San Lorenzo and replaced with Juncos as Manufacturing Site.	N/A
03	Changed GMDN code to 60579 as the old number was obsoleted. In the Standards section, deleted EN-980 and updated the revision date for EN ISO 15223-1:2016.	N/A
04	Updated EN ISO 13485 from 2012 to 2016 and updated the Standards Section to comply with V08-510-01.	N/A
05	Changed authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 10-Dec-2018
06	Added The Catalog Number with the Variant Code indicating the 198 case count.	N/A Feb 2019
07	Removed the "-" from the variant code.	N/A Feb 2019

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorized Representative:	Becton Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Manufacturing Site(s):	Becton Dickinson and Company 1575 Airport Road Sumter, SC 29153
Products:	**367300** BD Vacutainer® Luer Adapter
Classification:	EU Class I Sterile per Annex IX, Rule 1 of the Medical Device Directive (93/42/EEC). Canada Class I per Schedule 1, Part 1, Rule 7, sub-rule 1 of the Canadian Medical Device Regulations (CMDR), SOR//98-282 which states that all other non-invasive devices are classified as Class I in which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 60579 GMDN Term: Blood collection luer adapter

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:	EN 556-1 – 2001 EN 1041 - 2013 EN-ISO-15223-1:2016 EN ISO 11135 - 2014 EN ISO 11607-1 – 2010 EN ISO 11737-1 – 2006 EN ISO 13485 – 2016 EN ISO 14971 – 2012 EN ISO 14155 - 2011
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:	252-548
Date of issuance of original CE certificate:	19 May 1997

Date: 12 December 2018

Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

TITLE: **Declaration of Conformity for BD Vacutainer® Luer Adapter**

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Review and released – no updates necessary.	N/A
03	Changed GMDN code to 60579 as the old number was obsoleted. In the Standards section, deleted EN-980 and updated the revision date on EN ISO 15223-1-2016.	N/A
04	Updated Standards revision dates to comply with V08-510-01 rev. 04.	N/A
05	Updated authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 16-Nov-2018