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

Blood Collection Needles

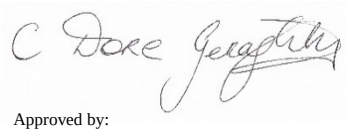
GMDN Code: 35209

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:	**252.190**
Original Approval:	**19 May 1997**
Last Amended on:	**25 May 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
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
Authorized Representative:	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Manufacturing Site(s):	**Manufacturing and Sterilization**: Becton Dickinson and Company 1575 Airport Road Sumter, SC 29153 **Alternate Sterilization Site**: Becton Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Products:	**368609** BD Vacutainer® Eclipse™ Blood Collection Needle, 21G x 1 ¼” **368610** BD Vacutainer® Eclipse™ Blood Collection Needle, 22G x 1 ¼”

Classification:	EU Class IIa per Annex IX, Section 2.2, Rule 6 of the Medical Device Directive (93/42/EEC) as amended by 2007/47/EC all surgically invasive devices intended for transient use, to which the exceptions do not apply. Canada Class II per Canadian Medical Devices Regulations, Schedule 1, Rule 1, which states the following "subject to subrules (2) and (3), 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: 35209 GMDN Term: Blood collection needle, basic

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 ISO 13485:2016 EN 1041:2008+A1:2013 EN ISO 14971:2019 EN ISO 10993 - Series EN 556-1:2001 ISO 11137-1:2006 AMD 2018 ISO 11137-2:2013 EN ISO 11737-1:2018 AMD 2021 EN ISO 11737-2:2020 EN-ISO-15223-1:2016 EN ISO 11607-1:2010 EN ISO 14155:2011 EN ISO 23908:2013
Standards – (Non- Harmonized)	ISO 9626 1991/Amd 1 2001 (E) ISO 6009 1992

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:	252-190
Date of issuance of original CE certificate:	19 May 1997

Date: 06-Dec-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 06-Dec-2022 | 10:15:14 PM GMT
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Anne Zavertnik
Vice President, Regulatory Affairs
Integrated Diagnostic Solutions

TITLE: Declaration of Conformity for BD Vacutainer® Eclipse™ Blood Collection Needles

REVISION HISTORY

Current Version Prepared By: Kelly Hilliger/Katherine Kenner Lemus

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release of the DoC	ECO 191884
02	Corrected address error.	N/A
03	Correct spelling of “Ecipse” in Product section to “Eclipse”.	N/A
04	Update DoC to new template for Medical Devices per MED-RA-001C. Update DoC to align with modification to the Tech File per ACR PAS 000351 – Addition of Plymouth as alternate sterilization for Eclipse Blood Collection Needles. Updated harmonized and non-harmonized standards to the DoC per MED-RA-001C.	N/A
05	Updated Standards section to remove EN-980 and updated the revision date of EN ISO 15223-1:2016 and moved it to the Harmonized Standards section from Non-Harmonized.	N/A
06	Changed the Authorized Signature to Bradford Spring., VP of Regulatory Affairs. Updated Standards comply with V08-510-01 Rev. 04.	N/A 22-Jan-2019
07	Changed the Authorized Rep to BD Switzerland Sarl; changed authorized signature to Kay Taylor.	N/A August 2019
08	Update Sterilization Standards EN ISO-11737-1:2018 and EN ISO-11737-2:2020 per BDVS-3030-04-29-085157 and S. Gray correction memo for EN ISO 11737-2:2020; updated header to IDS, Specimen Management.	N/A June 2020
09	Corrected standard reference from EN 1041:2013 to EN 1041:2008+A1:2013. Updated reference to ISO 11137-1:2015 to ISO 11137-1: 2006 AMD 2018 as a correction, update ISO 11137-2:2015 to ISO 11137-2:2013 as a correction and update ref to ISO 11737-1:2018 to ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739 Changed authorized signature to Anne Zavertnik.	N/A January 2022
10	Modified 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.	N/A May 2022

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	Corrected references to EN ISO 14971:2012 to the current standard EN ISO 14971:2019.	
11	Updated Authorized Representative: Becton Dickinson Ireland. to Becton Dickinson Ireland Limited.	N/A Nov 2022

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):	**Molding, Sub-Assembly, Assembly, Packaging and Holder**: Becton Dickinson and Company 1575 Airport Road Sumter, SC 29153 USA Becton Dickinson and Company 150 South First Avenue Broken Bow, NE 68822 USA
Products:	**368650** BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 21G x 1 ¼” **368651** BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 22G x 1 ¼”
Classification:	EU Class IIa per Annex IX, Section 2.2, Rule 6 of the Medical Device Directive (93/42/EEC) as amended by 2007/47/EC all surgically invasive devices intended for transient use, to which the exceptions do not apply. Canada Class II per Canadian Medical Devices Regulations, Schedule 1, Rule 1, which states the following “subject to subrules (2) and (3), 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: 35209 GMDN Term: Blood collection needle, basic

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 ISO 10993 - Series EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 11607-1::2010 EN ISO 11137-1:2015 AMD 2019 EN ISO 14155:2011 EN ISO 15223-1:2016 EN ISO 11737-1:2018 AMD 2021
Standards – (Non- Harmonized)	ASTM D999:2008 ASTM D-4169:2014 ISO 11737-1:2018/Amd 1:2021 ISO 11137-1:2006/Amd 2:2018
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:	252-190
Date of issuance of original CE certificate:	19 May 1997

Date: 01-Feb-2023

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 01-Feb-2023 | 9:27:11 PM GMT
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Anne Zavertnik
Vice President, Regulatory Affairs
Integrated Diagnostic Solutions

TITLE: Declaration of Conformity for BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder

REVISION HISTORY

Current Version Prepared By: Sravan Rajamani

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release of the DoC	N/A
02	Release new DoC template	N/A
03	Update Standards – remove EN980 and update revision date of EN ISO 15223-1 to 2016.	N/A
04	Updated Authorized Signature to Bradford Spring, VP Regulatory Affairs.	N/A 22-Jan-2019
05	Corrected typos in the catalog numbers.	N/A 08-Feb-2019
06	Changed the Authorized Rep to BD Switzerland Sarl; changed authorized signature to Kay Taylor.	N/A August 2019
07	Updated Standards section for: EN ISO 11737-1 – 2018 – updated from 2006 to 2018; updated header to IDS, Specimen Management.	N/A June 2020
08	Corrected standard reference for EN 1041 to EN 1041:2008+A1:2013 per IDSQUALITYPLAN7718. Updated ref to EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019, and update ref to EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739 Updated authorized signature to Anne Zavertnik	N/A January 2022
09	Modified 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 Removed reference to ISO 1041:2013 per IDSQUALITYPLAN7718 Added ISO equivalent non-harmonized standards for EN ISO 11137-1:2015 AMD 2019 and EN ISO 11737-1:2018 AMD 2021.	N/A May 2022
10	Revised Authorized Rep name from “Ltd.” to “Limited”	N/A Jan 2023