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