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 Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
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 13485:2012 EN 1041:2008 EN ISO 14971:2012 EN ISO 10993 - Series EN 556-1:2001 EN ISO 11137-1:2006 EN ISO 11137-2:2006 EN ISO 11737-1:2006 EN ISO 11737-2:2009 EN-ISO-15223-1:2016 EN ISO 11607-1:2009 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: 05-March 2018

Vernon Brown
Director Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

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