# EC DECLARATION OF CONFORMITY

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| **Legal Manufacturer:** | Becton Dickinson and Company (BD)<br>1 Becton Drive<br>Franklin Lakes, NJ 07417 USA |
| **Authorised Representative:** | Becton Dickinson and Company<br>Belliver Industrial Estate<br>Belliver Way<br>Roborough<br>Plymouth PL6 7BP UK |
| **Manufacturing Site(s):** | **Manufacturing and Sterilization**:<br>Becton Dickinson and Company<br>1575 Airport Road<br>Sumter, SC 29153<br>**Alternate Sterilization Site**:<br>Becton Dickinson and Company<br>Belliver Industrial Estate<br>Belliver Way<br>Roborough<br>Plymouth PL6 7BP UK |
| **Products:** | **368609** BD Vacutainer® Eclipse™ Blood Collection Needle, 21G x 1 ¼"<br>**368610** BD Vacutainer® Eclipse™ Blood Collection Needle, 22G x 1 ¼" |
| **Classification:** | EU<br>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.<br><br>Canada<br>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<br>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.

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| **Standards – (Harmonized)** | EN ISO 13485:2012<br>EN 1041:2008<br>EN ISO 14971:2012<br>EN ISO 10993 - Series<br>EN 556-1:2001<br>EN ISO 11137-1:2006<br>EN ISO 11137-2:2006<br>EN ISO 11737-1:2006<br>EN ISO 11737-2:2009<br>EN-ISO-15223-1:2016<br>EN ISO 11607-1:2009<br>EN ISO 14155:2011<br>EN ISO 23908:2013 |
| **Standards – (Non- Harmonized)** | ISO 9626 1991/Amd 1 2001 (E)<br>ISO 6009 1992 |
| **Notified Body:** | National Standards Association of Ireland (NSAI)<br>1 Swift Square<br>Northwood<br>Santry, Dublin 9, Ireland<br>Phone: 353 (01) 807-3800<br>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 |
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