1 Becton Drive
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bd.com

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:	**Molding, Sub Assembly, Assembly, Packaging and Holder** Becton, Dickinson and Company (BD) 1575 Airport Rd. Sumter, SC 29153 USA Becton Dickinson and Company (BD) 150 South First Avenue Broken Bow, NE 68822 USA
Products:	**368650** BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 21G x 1-1/4" **368651** BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder, 22G x 1-1/4"
Classification:	EU The BD Vacutainer® Eclipse Blood Collection Needle with Pre-Attached Holder is a 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 The BD Vacutainer® Eclipse Blood Collection Needle with Pre-Attached Holder is a 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

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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Harmonized Standards:	EN556-1 :2001 EN980:2008 EN1041:2008 EN ISO 10993 Series I.S. EN ISO 13485 :2012 EN ISO 14971 :2012 EN ISO 11607-1 :2009 EN ISO 11137-1:2006 EN ISO 11737-1 :2006 EN ISO 14155 :2011 EN ISO15223-1 :2012
Non-Harmonized Standards	ASTM D999:2008 ASTM D-4169:2014
Notified Body:	National Standards Authority 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:	Original Approval: 19 May 1997

Document Reference Number: VTF0043-02

Date: 09 November 2016

Vernon Brown
Director Regulatory Affairs
BD Life Sciences – Preanalytical Systems

Date: 14th November 2016

Lorna Darroch
Manager Regulatory Affairs
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Authorized Representative

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Revision History

Current Version Prepared By: P. Amato

Rev.	Revision Description	Releasing ECO (if applicable)
2	Initial Release of new DOC template which incorporates requirements of MED-RA-001C. Previous revision histories are contained in the DOC up to Revision 2.	NA