

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):	Becton Dickinson and Company 1575 Airport Road Sumter, SC 29153
Products:	367300 BD Vacutainer® Luer Adapter
Classification:	EU Class I Sterile per Annex IX, Rule 1 of the Medical Device Directive (93/42/EEC). Canada Class I per Schedule 1, Part 1, Rule 7, sub-rule 1 of the Canadian Medical Device Regulations (CMDR), SOR//98-282 which states that all other non-invasive devices are classified as Class I in which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC
GMDN:	GMDN Code: 60579 GMDN Term: Blood collection luer adapter

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:	EN 556-1 – 2001 EN 1041 - 2013 EN-ISO-15223-1:2016 EN ISO 11135 - 2014 EN ISO 11607-1 – 2010 EN ISO 11737-1 – 2006 EN ISO 13485 – 2016 EN ISO 14971 – 2012 EN ISO 14155 - 2011
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:	252-548
Date of issuance of original CE certificate:	19 May 1997

Date: *27 April 2018*



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

**TITLE: Declaration of Conformity for
BD Vacutainer® Luer Adapter**

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Review and released – no updates necessary.	N/A
03	Changed GMDN code to 60579 as the old number was obsoleted. In the Standards section, deleted EN-980 and updated the revision date on EN ISO 15223-1-2016.	N/A
04	Updated Standards revision dates to comply with V08-510-01 rev. 04.	N/A