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 (BD) Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Manufacturing Site(s):	**Manufacturing**: BD Caribe, Ltd. Road 31, KM 24.3 Juncos, PR 00777-4010
Products:	**364902** BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Mutiple Sample Adapter (200 count per case) **364902 00** BD Vacutainer® Luer Lok™ Access Device Holder with Pre-Attached Mutiple Sample Adapter (198 count per case)
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 1 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.

TITLE: **Declaration of Conformity for BD Vacutainer® Luer-Lok™ Access Device Holder With Pre-Attached Multiple Sample Adapter**

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: February 5, 2019

Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

TITLE: Declaration of Conformity for
BD Vacutainer® Luer Lok™ Access Device Holder
With Pre-Attached Multiple Sample Adapter

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Removed San Lorenzo and replaced with Juncos as Manufacturing Site.	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 for EN ISO 15223-1:2016.	N/A
04	Updated EN ISO 13485 from 2012 to 2016 and updated the Standards Section to comply with V08-510-01.	N/A
05	Changed authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 10-Dec-2018
06	Added The Catalog Number with the Variant Code indicating the 198 case count.	N/A Feb 2019
07	Removed the "-" from the variant code.	N/A Feb 2019