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 150 South First Avenue Broken Bow, NE 68822 USA Becton Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Products:	**364305** BD Vacutainer® Plus Blood Collection Tubes Buffered Sodium Citrate: 0.3mL – 0.109M **368273** BD Vacutainer® Plus Blood Collection Tubes 9NC 0.109M 0.2ml
Classification:	EU Non Annex II In Vitro Diagnostic of 98/79/EC Canada Class I
Conformity Assessment Route:	EU - Annex III of 98/79/EC Canada – Schedule 1, Part 2, Rule (8) Canadian Medical Device Regulations SOR/98-282
GMDN:	GMDN Code: 42585 GMDN Term: Evacuated blood collection tube, sodium citrate

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 ISO 11137-1:2015 EN 556-1:2001 EN ISO 13485:2016 EN-ISO-15223-1:2016 EN 14820:2004 CLSI GP39-A6:2010 EN ISO 14971:2012
Notified Body:	Not Applicable
CE Certificate Number:	Self Certified
Date of issuance of original CE certificate:	Not Applicable

Date: 03 May 2018

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

TITLE: **Declaration of Conformity for BD Vacutainer® Tubes containing Sodium Citrate**

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	N/A
02	Added Plymouth UK as the Manufacturing Site for 364305 and 368273. Updated name of Authorized Representative.	N/A
03	Removed catalog 363905 as BD Franklin Lakes is not the Legal Manufacturer.	N/A
04	Removed Catalog No.'s 363048, 363079 and 363097, Plymouth product and the labeling identifies Plymouth as the Legal Manufacturer as requested by European Regulatory. Removed obsolete catalog 368926 BD Vacutainer® 0.105M 9NC Tubes.	N/A
05	Obsolete catalog 368932 BD Vacutainer® Blood Collection Tubes 0.129< 9NC per ACR 000116-00.	N/A
06	Added catalog 364308 per ACR PAS 000338-00. Also deleted information of the Notified Body as this product is self-certified.	N/A
07	Removed catalog 364308 as this catalog number will not be released. Added Standards per Tech File.	N/A
08	Updated "Standards" revision dates as per V08-510-01.	N/A