1 Becton Drive
Franklin Lakes, New Jersey
tel: 201.847.6800
www.bd.com

BD
Helping all people live healthy lives

DECLARATION OF CONFORMITY

Legal Manufacturer:	*Name and Address* Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA	
Authorized Representative:	*Name and Address* Regulatory Affairs Manager, PAS Europe BD Diagnostics, Preanalytical Systems Belliver Industrial Estate Plymouth, PL6 7BP, UK	
Products:	Product Family • BD Vacutainer ® PPT™ Plasma Preparation Tube	
Device Name:	Catalog Numbers **362791** BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA)9.0 mg **362794** BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg **362795** BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg **362799** BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg **362800** BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	GMDN Code: 47587 GMDN Term: Evacuated blood collection tube IVD, K2 EDTA/gel separator
Classification:	*Provide Class of Device according to IVDD* **European Union** Annex III of 98/79/EC **Canada** Class 1	
Conformity Assessment Route:	*According to IVDD* Annex III of 98/79/EC **Canada** Schedule I, Part 2, Rule (8) Canadian Medical Device Regulations SOR/98-282	

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC of 27 October 1998 concerning *in vitro diagnostic devices*. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	*Name and Address* National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838

EC Certificate number:	N/A (Self Certified)
Start of CE marking:	Original Approval: N/A
Manufacturing Site:	*Name and Address* **Manufacturing and Sterilization** BD Diagnostics, Preanalytical Systems 150 South First Street Broken Bow, NE 68822 USA

Refer: VTF0047-02 PPT Declaration of Conformity

Date: February 12, 2014

Arthur Kawasaki
WW Director, Regulatory Affairs
BD Diagnostics-Preanalytical Systems

Revision History		
Current Revision Prepared By: MaryAnn Pruzinsky **Training Requirements For This Revision:** Regulatory Affairs [ ] No Training Required [X] Read Only [ ] Classroom Training [ ] Manufacturing facilities are to incorporate applicable sections of this document into their quality system.		
REVISION RECORD		
Rev. No.	**Revision Description**	**ECO No.**
01	Release the Declaration of Conformity for BD Vacutainer® PPT™ Plasma Preparation Tube	ECO195632