



DECLARATION OF CONFORMITY

Legal Manufacturer:	<i>Name and Address</i> Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA	
Authorized Representative:	<i>Name and Address</i> Regulatory Affairs Manager, PAS Europe BD Diagnostics, Preanalytical Systems Belliver Industrial Estate Plymouth, PL6 7BP, UK	
Products:	Product Family <ul style="list-style-type: none"> • 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:	<i>Provide Class of Device according to IVDD</i> European Union Annex III of 98/79/EC Canada Class 1	
Conformity Assessment Route:	<i>According to IVDD</i> Annex III of 98/79/EC Canada Schedule I, Part 2, Rule (8) Canadian Medical Device Regulations SOR/98-282	

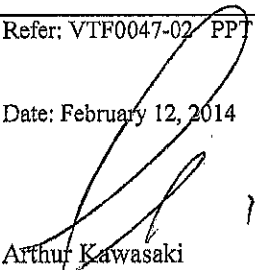
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC of 27 October 1998 concerning *in vitro diagnostic devices*. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	<i>Name and Address</i> National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
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EC Certificate number:	N/A (Self Certified)
Start of CE marking:	Original Approval: N/A
Manufacturing Site:	<i>Name and Address</i> 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		
<p>Current Revision Prepared By: MaryAnn Pruzinsky</p> <p>Training Requirements For This Revision: Regulatory Affairs</p> <p><input type="checkbox"/> No Training Required <input checked="" type="checkbox"/> Read Only <input type="checkbox"/> Classroom Training</p> <p><input type="checkbox"/> Manufacturing facilities are to incorporate applicable sections of this document into their quality system.</p>		
REVISION RECORD		
Rev. No.	Revision Description	ECO No.
01	Release the Declaration of Conformity for BD Vacutainer® PPT™ Plasma Preparation Tube	ECO195632