

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® Blood Collection Tubes containing Sodium Fluoride and Potassium Oxalate (Glucose Tubes) 	
Device Name:	Catalog Numbers 366659 BD Vacutainer® FX 5 mg - 4 mg Blood Collection Tubes 368920 BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes 368921 BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes 367934 BD Vacutainer® FX 5mg 4mg Plus Tubes 367935 BD Vacutainer® FX 10mg:8mg Plus Blood Collection Tubes	GMDN Code: 47591 GMDN Term: BD Vacutainer® Sodium Fluoride and Potassium Oxalate tube
Classification:	<i>Provide Class of Device according to IVDD</i> European Union Annex III of 98/79/EC Canada Class I	
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	

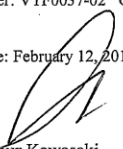
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC of 27 October 1998 concerning *in vitro diagnostic devices*. All supporting documentation is retained under the premises of the manufacturer.

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
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: VTF0037-02 Glucose Tubes 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 <input type="checkbox"/> No Training Required <input checked="" type="checkbox"/> Read Only <input type="checkbox"/> Classroom Training <input type="checkbox"/> 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® Fluoride Tubes	ECO195632