

## 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"> <li>BD Vacutainer® Blood Collection Tubes containing Sodium Fluoride and Potassium Oxalate (Glucose Tubes)</li> </ul>	
Device Name:	Catalog Numbers <b>366659</b> BD Vacutainer® FX 5 mg - 4 mg Blood Collection Tubes <b>368920</b> BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes <b>368921</b> BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes <b>367934</b> BD Vacutainer® FX 5mg 4mg Plus Tubes <b>367935</b> 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> <b>European Union</b> Annex III of 98/79/EC  <b>Canada</b> Class I	
Conformity Assessment Route:	<i>According to IVDD</i> Annex III of 98/79/EC  <b>Canada</b> Schedule I, Part 2, Rule (8) Canadian Medical Device Regulations SOR/98-282	

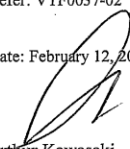
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC of 27 October 1998 concerning *in vitro diagnostic devices*. All supporting documentation is retained under the premises of the manufacturer.

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> <b>Manufacturing and Sterilization</b> 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

<b>Revision History</b>		
<b>Current Revision Prepared By:</b> MaryAnn Pruzinsky		
<b>Training Requirements For This Revision:</b> 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.		
<b>REVISION RECORD</b>		
<b>Rev. No.</b>	<b>Revision Description</b>	<b>ECO No.</b>
01	Release the Declaration of Conformity for BD Vacutainer® Fluoride Tubes	ECO195632