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

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® 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:	*Provide Class of Device according to IVDD* **European Union** Annex III of 98/79/EC **Canada** Class I	
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: VTF0037-02 Glucose Tubes Declaration of Conformity

Date: February 12, 2014

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

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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® Fluoride Tubes	ECO195632