



1 Becton Drive
Franklin Lakes, New Jersey
tel: 201.847.6800

bd.com

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> Becton, Dickinson and Company Belliver Roborough Plymouth PL6 7BP United Kingdom	
Products:	Product Family <ul style="list-style-type: none"> BD Vacutainer® Serum and SST™ Blood Collection Tubes for Serum Determinations 	
Device Name:	Catalog Numbers 367985 BD Vacutainer® SST™ Plus Blood Collection Tubes 368825 BD Vacutainer® SST™ Plus Blood Collection Tubes 367819 BD Vacutainer® Serum / CAT Plus Blood Collection Tubes	Catalog Numbers: 367985 , 368825 GMDN Code: 41128 GMDN Term: Evacuated blood collection tube IVD, clot activator/gel separator Catalog Numbers: 367819 GMDN Code: 42386 GMDN Term: Evacuated blood collection tube IVD, clot activator
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> Catalogue Number 367819, 367985 & 368825 Becton, Dickinson and Company 1575 Airport Rd. Sumter, SC 29153 USA

Refer: **VTF0046-02** SST Tubes Declaration of Conformity

Date: November 14, 2016



14 November 2016

Vernon Brown

Regulatory Affairs Director
BD Life Sciences-Preanalytical Systems

Revision History		
Current Revision Prepared By: P. Amato 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® Serum and SST™ Blood Collection Tubes for Serum Determinations	ECO195632
02	Deleted discontinued catalog 367782. Corrected European Representative name	NA
03	Deleted Manufacturing site for discontinued catalog 367782. Added catalog numbers 368906 and 368910 and their manufacturing location.	NA
04	Deleted catalog numbers 368906 and 368910 and their manufacturing location as per ACR PAS000394-02. Updated manufacturing site name and address to match technical file.	NA