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



DECLARATION OF CONFORMITY

Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA Name and Address Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP United Kingdom Products: Product Family ■ BD Vacutainer® Urine Collection Devices Device Name: Catalog Numbers 364940 BD Vacutainer® Urine Transfer Unit 364940 GMDN Code: 58157 GMDN Term: Urine transfer, IVD GMDN Term: 24-hour urine specimen container IVD, no-additive 364982 BD Vacutainer® Urine Collection Cups 364982 GMDN Code: 57919 GMDN Term: 24-hour urine specimen container IVD, no-additive 17D, no-additive sterile 364938 BD Vacutainer® Z (No Additive) Plus Urine Tube 365000 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical 364944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical 364944 BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate 364955 BD Vacutainer® Plus C&S Boric Acid 364949, 364953, 364958, 364959, and 364969 GMDN Code: 38151	Legal Manufacturer:	Name and Address		
Authorized Representative: Name and Address Becton, Dickinson and Company Belliver Way Roborough Plymouth PL6 7BP United Kingdom		Becton, Dickinson and Company (BD)		
Authorized Representative: Name and Address Becton, Dickinson and Company Belliver Industrial Estate Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP United Kingdom		ABS BOWN STRANSCORD-MANAGED COLUMN COPES		
Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP United Kingdom Products: Product Family • BD Vacutainer® Urine Collection Devices Device Name: Catalog Numbers 364940 BD Vacutainer® Urine Transfer Unit 364982 BD Vacutainer™ 24 Hour Urine Specimen Container 364982 BD Vacutainer™ 24 Hour Urine Specimen Container 364982 BD Vacutainer™ 24 Hour Urine Specimen Container 364981 BD Vacutainer® Urine Collection Cups GMDN Term: 24-hour urine specimen container IVD, no-additive 364941 BD Vacutainer® Z (No Additive) Plus Urine Tube 365000 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical Urine Tube - Conical S64944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical S64944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical S64944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical S64944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical S64944 BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical S64945 BD Vacutainer® C&S Boric Acid Kit S64946 BD Vacutainer® Plus C&S Boric Acid S64947 Add955, 364958, 364959, and 364969	Authorized Dongsontation			
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Sodium Borate/Formate			_ ^	
364969 BD Vacutainer™ Boric Acid, Sodium Formate For Urine Only 6ml 13x100mm 364992, 365017 and			364992 365017 and	
Formate For Urine Only 6ml 13x100mm 364992, 365017 and 368832		Formate For Orme Only only 13x100mm		
364992 BD Vacutainer® Urine Analysis GMDN Code: 57924		364992 BD Vacutainer® Urine Analysis		
Preservative Tube		Preservative Tube		
365017 BD Vacutainer® Urinalysis Preservative GMDN Term: Evacuated		365017 BD Vacutainer® Urinalysis Preservative	GMDN Term: Evacuated	

	Plus Urine Tube 368832 BD Vacutainer® Urinalysis Preservative Plus Urine Tube	urine specimen container IVD, ethylparaben/Sodium propionate/chlortexidine
Classification:	Provide Class of Device according to IVDD European Union Urine collection products described herein are non I of Directive 98/79/EC of the European Parliament a October 1998 on in vitro diagnostic medical devices Canada Class I	nd of the Council of 27
Conformity Assessment Route:	According to IVDD Annex III of Directive 98/79/EC Canada Schedule I, Section 6, Part 1, Rule (7) Subrule (1) 0 Regulations SOR/98-282	Canadian Medical Device

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
	BD Diagnostics, Preanalytical Systems
	Becton, Dickinson and Company (BD)
	Address: 150 South First Street
	Broken Bow, NE 68822 USA
	Becton, Dickinson and Company
	Belliver Industrial Estate
	Belliver Way
	Roborough
	Plymouth
	PL6 7BP
	United Kingdom

Refer: VTF0022-02 Urine Collection Declaration of Conformity (Rev .04)

Date: January 13, 2016
Ellen Hiller

Eileen Hiller

Senior Staff Specialist, Regulatory Affairs BD Life Sciences-Preanalytical Systems

Revision History			
Current Revision Prepared By:	Pasquale Amato		
Training Requirements For Thi	s Revision: Regulate	ory Affairs	
[] No Training Required	[X] Read Only	[] Classroom Training	
[] Manufacturing facilities are to quality system.	incorporate applicable	e sections of this document into their	
	DEVICE ON DEC	ODD	

Rev. No.	Revision Description	ECO No.
01	Release the Declaration of Conformity for BD Vacutainer® Urine Collection Devices	ECO195632
02	Added Plymouth manufacturing site	NA
03	Corrected typo Catalog #364941 BD Vacutainer® Urine Collection Cups	NA
04	Added 368832 BD Vacutainer® Urinalysis Preservative Plus Urine Tube and updated Authorized Representative section. Release date 1/13/16	NA