

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 Industrial Estate Belliver Way Roborough Plymouth PL6 7BP United Kingdom	
Products:	Product Family <ul style="list-style-type: none"> • <i>BD Vacutainer® Urine Collection Devices</i> 	
Device Name:	Catalog Numbers 364940 BD Vacutainer® Urine Transfer Unit 364982 BD Vacutainer™ 24 Hour Urine Specimen Container 364941 BD Vacutainer® Urine Collection Cups 364938 BD Vacutainer® Z (No Additive) Plus Urine Tube 365000 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 Sodium Borate/Formate 364958 BD Vacutainer® Plus C&S Boric Acid Sodium Borate/Formate 364959 BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate 364969 BD Vacutainer™ Boric Acid, Sodium Formate For Urine Only 6ml 13x100mm 364992 BD Vacutainer® Urine Analysis Preservative Tube 365017 BD Vacutainer® Urinalysis Preservative	364940 GMDN Code: 58157 GMDN Term: Urine transfer, IVD 364982 GMDN Code: 57919 GMDN Term: 24-hour urine specimen container IVD, no-additive 364941 GMDN Code: 47776 GMDN Term: General specimen container IVD, no-additive sterile 364938 and 365000 GMDN Code: 58158 GMDN Term: Evacuated urine specimen container IVD, no-additive 364944, 364955, 364958, 364959, and 364969 GMDN Code: 58151 GMDN Term: Evacuated urine specimen container IVD, multiple preservative 364992, 365017 and 368832 GMDN Code: 57924 GMDN Term: Evacuated

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

Eileen Hiller

Eileen Hiller

Senior Staff Specialist, Regulatory Affairs

BD Life Sciences-Preanalytical Systems

Revision History		
Current Revision Prepared By: Pasquale 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® 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