

## 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"> <li>• <i>BD Vacutainer® Urine Collection Devices</i></li> </ul>	
Device Name:	Catalog Numbers <b>364940</b> BD Vacutainer® Urine Transfer Unit  <b>364982</b> BD Vacutainer™ 24 Hour Urine Specimen Container  <b>364941</b> BD Vacutainer® Urine Collection Cups  <b>364938</b> BD Vacutainer® Z (No Additive) Plus Urine Tube <b>365000</b> BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical  <b>364944</b> BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate <b>364955</b> BD Vacutainer® Plus C&S Boric Acid Sodium Borate/Formate <b>364958</b> BD Vacutainer® Plus C&S Boric Acid Sodium Borate/Formate <b>364959</b> BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate <b>364969</b> BD Vacutainer™ Boric Acid, Sodium Formate For Urine Only 6ml 13x100mm  <b>364992</b> BD Vacutainer® Urine Analysis Preservative Tube <b>365017</b> BD Vacutainer® Urinalysis Preservative	<b><u>364940</u></b> GMDN Code: 58157  GMDN Term: Urine transfer, IVD  <b><u>364982</u></b> GMDN Code: 57919  GMDN Term: 24-hour urine specimen container IVD, no-additive  <b><u>364941</u></b> GMDN Code: 47776  GMDN Term: General specimen container IVD, no-additive sterile  <b><u>364938 and 365000</u></b> GMDN Code: 58158  GMDN Term: Evacuated urine specimen container IVD, no-additive  <b><u>364944, 364955, 364958, 364959, and 364969</u></b> GMDN Code: 58151  GMDN Term: Evacuated urine specimen container IVD, multiple preservative  <b><u>364992, 365017 and 368832</u></b> GMDN Code: 57924  GMDN Term: Evacuated

	Plus Urine Tube <b>368832</b> 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> <b>European Union</b> 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  <b>Canada</b> Class I	
Conformity Assessment Route:	<i>According to IVDD</i> Annex III of Directive 98/79/EC  <b>Canada</b> 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

<b>Revision History</b>		
<b>Current Revision Prepared By:</b> Pasquale Amato		
<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>		
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 <b>368832</b> BD Vacutainer® Urinalysis Preservative Plus Urine Tube and updated Authorized Representative section. Release date 1/13/16	NA