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Document No. DS-Viper\_CollectDev-DOC

Revision/Version: 02

# EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company				
	7 Loveton Circle				
	Sparks, Maryland 21152 USA				
Manufacturer SRN:	US-MF-000	01891	0		
Authorised Representative:	Becton Dickinson Ireland Ltd.				
	Donore Roa	ıd, Dro	gheda		
	Co. Louth,	A92 Y	W26		
	Ireland				
Authorised Representative SRN:	IE-AR-0000	007610			
Product:	Catalog Number		Product	Product Trade Name	
	44136			BD Specimen Tubes and Caps for use on the BD Viper <sup>™</sup> System	
	441362		BD Urine Preservative Transport for the BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Amplified DNA Assays		
	441361		BD Swab Diluent for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays		
	441444		BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays		
	441357		BD ProbeTec <sup>™</sup> Q <sup>x</sup> Collection Kit for Endocervical or Lesion Specimens		
	441358BD Male Urethral Specimen Collect for the BD ProbeTec™ Qx Amplific Assays				
Basic UDI-DI:	Catalog	Pro	oduct Trade Name	Basic UDI-DI	
	Number				
	441360	Caps	pecimen Tubes and for use on the BD ™ System	038290IEHRMMUH8T	
	441362	Trans Probe	Jrine Preservative sport for the BD eTec™ Q <sup>x</sup> Amplified Assays	038290ISIVPOXCJY	
	441361	BD P	wab Diluent for the robeTec™ Q <sup>x</sup> lified DNA Assays	038290IZBUIXJAHX	
	441444	BD L Cytol (LBC the B	iquid-Based logy Specimen ♡ Dilution Tubes for D ProbeTec <sup>™</sup> Q <sup>x</sup> lified DNA Assays	038290KJMCIFTK7N	



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				1
	441357	BD ProbeTec <sup>TM</sup> $Q^x$		038290MBATTEPZ8D
		Collection Kit for		
		Endocervical or Lesio	on	
		Specimens		
	441358	BD Male Urethral		038290MDUAMJPQ9Q
		Specimen Collection	Kit	
		for the BD ProbeTec <sup>1</sup>		
		Amplified DNA Assa	~	
			iys	
Risk Class and Rule :				1
	Catalog Number	Product Trade Na	me	Risk Class and Rule
	441360	BD Specimen Tubes	and	Class A, Rule 5(a)
		Caps for use on the B		
		Viper <sup>™</sup> System		
	441362	BD Urine Preservativ	ie.	Class A, Rule 5(c)
	441502	Transport for the BD	C	
		ProbeTec <sup>TM</sup> $Q^x$ Ampl	ified	
		< I	meu	
	444255	DNA Assays	.1	
	441361	BD Swab Diluent for	the	Class A, Rule 5(c)
		BD ProbeTec <sup>™</sup> Q <sup>x</sup>		
		Amplified DNA Assa	ays	
	441444	BD Liquid-Based		Class A, Rule 5(c)
		Cytology Specimen		
		(LBC) Dilution Tube	s for	
		the BD ProbeTec <sup>™</sup> (		
		Amplified DNA Assa	~	
	441357	BD ProbeTec <sup>TM</sup> $Q^x$	<i>x</i>	Class A Bula 5(a)
	44133/	Collection Kit for		Class A, Rule 5(c)
		Endocervical or Lesio	on	
		Specimens		
	441358	BD Male Urethral		Class A, Rule 5(c)
		Specimen Collection		
		for the BD ProbeTec <sup>7</sup>		
		Amplified DNA Assa	ays	
				<b>.</b>
Intended Purpose:	Catalog Number	Product Trade Name		Intended Purpose
	441360	BD Specimen	BD S	pecimen Tubes and Caps
		Tubes and Caps		tended to be used with
		for use on the BD		iper Systems.
		Viper <sup>™</sup> System	י ענ	iper Systems.
	441362	BD Urine	The U	Jrine Preservative
	441302			
	441302	Preservative	Trans	port for the BD
	441302	Preservative Transport for the		port for the BD cTec™ Q <sup>x</sup> Amplified
	441302		Probe	



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	Q <sup>x</sup> Amplified DNA Assays	designed to preserve and transport <i>Chlamydia</i> <i>trachomatis</i> and <i>Neisseria</i> <i>gonorrhoeae</i> in male and female urine specimens from symptomatic and asymptomatic individuals prior to processing for analysis with the BD ProbeTec <sup>TM</sup> CT Q <sup>x</sup> and GC Q <sup>x</sup> Amplified DNA Assays on the BD Viper <sup>TM</sup> System.
441361	BD Swab Diluent for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	BD Swab Diluent for the BD ProbeTec Q <sup>x</sup> Amplified DNA Assays is intended to be used with BD ProbeTec CT/GC/TV/HSV1&2 Q <sup>x</sup> Amplified DNA Assays on the BD Viper System in Extracted Mode and the BD ProbeTec CT/GC Q <sup>x</sup> Amplified DNA Assays on the BD Viper LT System.
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	The Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Amplified DNA Assays are designed to allow for detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in gynecological specimens that are collected in BD SurePath <sup>TM</sup> Preservative Fluid or PreservCyt <sup>®</sup> Solution and tested with the BD ProbeTec <sup>TM</sup> CT Q <sup>x</sup> and GC Q <sup>x</sup> Amplified DNA Assays on the BD Viper <sup>TM</sup> System using an aliquot that is removed prior to processing for either the BD SurePath <sup>TM</sup> or ThinPrep <sup>®</sup> Pap test.
441357	BD ProbeTec <sup>™</sup> Q <sup>x</sup> Collection Kit for Endocervical or Lesion Specimens	The BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Collection Kit for Endocervical or Lesion Specimens is used to collect and transport patient endocervical specimens to the laboratory for testing with the BD ProbeTec <sup>TM</sup> CT/GC Q <sup>x</sup> Amplified DNA Assays on the BD Viper <sup>TM</sup> System and the BD ProbeTec <sup>TM</sup> <i>Trichomonas</i>



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			vaginalis (TV) Q <sup>x</sup> Amplified DNA Assay on the BD Viper <sup>™</sup> System in Extracted Mode. The Collection Kit also may be used to collect and transport external anogenital lesion specimens to the laboratory for testing with the BD ProbeTec <sup>™</sup> HSV1&2 Q <sup>x</sup> Amplified DNA Assays on the BD Viper <sup>™</sup> System in Extracted Mode.
	441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	The Male Urethral Specimen Collection Kit for the BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Amplified DNA Assays is used to collect and transport male patient urethral specimens to the laboratory for testing with the BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Amplified DNA Assays on the BD Viper <sup>TM</sup> System.
Notified Body:	Not applicable	e, devices self-certifi	ed
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):			

Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.

## **Conformity Assessment Route:**

ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A
	EC Certificate Expiration Date: N/A
ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A
	EC Certificate Expiration Date: N/A
ANNEX X Type Examination	EC CERTIFICATE No.: N/A
	EC Certificate Expiration Date: N/A
ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A
	EC Certificate Expiration Date: N/A
ANNEX I & II+III	N/A



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## **Common Specifications (CS):**

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for these products.

### **Devices Covered by this DoC:**

SKU#	Device Name	<b>Device Class</b>
441360	BD Specimen Tubes and Caps for use on the BD Viper <sup>TM</sup> System	Class A
441362	BD Urine Preservative Transport for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	Class A
441361	BD Swab Diluent for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	Class A
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	Class A
441357	BD ProbeTec <sup>TM</sup> Q <sup>x</sup> Collection Kit for Endocervical or Lesion Specimens	Class A
441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec <sup>™</sup> Q <sup>x</sup> Amplified DNA Assays	Class A

Authorised Signatory:			
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs		
On behalf of:	Becton, Dickinson and Company		
Place of Issue:	Sparks, MD, USA		
Date of Issue:	10-Nov-2022		
Signature:	DocuSigned by: Iww & & Wirtwik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022   11:36:25 PM GMT DC6A638A32E64A8A91F9D8DE330F0415		



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## **DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial Release
02	Changed to CBI-058 FRM24 Rev.04 template. Included "Catalog Number" in Intended purpose section. Removed "Not Available" from Common Specifications table. Removed Rules from "Device Class" of Devices covered by this Doc. Updated "On behalf of" with Legal Manufacturer's Name. Formatting changes.