EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA
Manufacturer SRN:	US-MF-000018910
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610

Product:

Catalog Number	Product Trade Name
441360	BD Specimen Tubes and Caps for use on the BD Viper™ System
441362	BD Urine Preservative Transport for the BD ProbeTec™ Q^x Amplified DNA Assays
441361	BD Swab Diluent for the BD ProbeTec™ Q^x Amplified DNA Assays
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec™ Q^x Amplified DNA Assays
441357	BD ProbeTec™ Q^x Collection Kit for Endocervical or Lesion Specimens
441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x Amplified DNA Assays

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
441360	BD Specimen Tubes and Caps for use on the BD Viper™ System	038290IEHRMMUH8T
441362	BD Urine Preservative Transport for the BD ProbeTec™ Q^x Amplified DNA Assays	038290ISIVPOXCJY
441361	BD Swab Diluent for the BD ProbeTec™ Q^x Amplified DNA Assays	038290IZBUIXJAHX
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec™ Q^x Amplified DNA Assays	038290KJMCIFTK7N

441357	BD ProbeTec™ Q^x Collection Kit for Endocervical or Lesion Specimens	038290MBATTEPZ8D
441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x Amplified DNA Assays	038290MDUAMJPQ9Q

Risk Class and Rule :

Catalog Number	Product Trade Name	Risk Class and Rule
441360	BD Specimen Tubes and Caps for use on the BD Viper™ System	Class A, Rule 5(a)
441362	BD Urine Preservative Transport for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A, Rule 5(c)
441361	BD Swab Diluent for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A, Rule 5(c)
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A, Rule 5(c)
441357	BD ProbeTec™ Q^x Collection Kit for Endocervical or Lesion Specimens	Class A, Rule 5(c)
441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A, Rule 5(c)

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
441360	BD Specimen Tubes and Caps for use on the BD Viper™ System	BD Specimen Tubes and Caps are intended to be used with BD Viper Systems.
441362	BD Urine Preservative Transport for the BD ProbeTec™	The Urine Preservative Transport for the BD ProbeTec™ Q^x Amplified DNA Assays (Q^x UPT) is

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

			vaginalis (TV) Q^x Amplified DNA Assay on the BD Viper™ 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™ HSV1&2 Q^x Amplified DNA Assays on the BD Viper™ System in Extracted Mode.
	441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x Amplified DNA Assays	The Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x Amplified DNA Assays is used to collect and transport male patient urethral specimens to the laboratory for testing with the BD ProbeTec™ Q^x Amplified DNA Assays on the BD Viper™ System.
Notified Body:	Not applicable, devices self-certified		

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

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	Device Class
441360	BD Specimen Tubes and Caps for use on the BD Viper™ System	Class A
441362	BD Urine Preservative Transport for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A
441361	BD Swab Diluent for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A
441444	BD Liquid-Based Cytology Specimen (LBC) Dilution Tubes for the BD ProbeTec™ Q^x Amplified DNA Assays	Class A
441357	BD ProbeTec™ Q^x Collection Kit for Endocervical or Lesion Specimens	Class A
441358	BD Male Urethral Specimen Collection Kit for the BD ProbeTec™ Q^x 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: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:36:25 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

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.