

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	
	442839	BD Viper™ LT System	
	442950	BD PREWARM HEATER	
	442958	BD Viper™ LT System SDA Accessory kit	
	442948	BD Viper LT System software	
	441129	BD FOX™ Extraction Tubes	
	441994	BD Viper™ SDA Extraction Reagent Trough with Piercing Tool	
	442967	BD Viper™ LT System PCR Accessory Kit	
	442957	BD Viper™ LT System PCR Tube / Tray Kit	
	442841	BD Viper™ PCR Extraction Reagent Trough with Piercing Tool	
	441992	BD FOX™ PCR Extraction Tubes	
	443747	BD Key Card for the BD Viper™ LT System	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	442839	BD Viper™ LT System	038290FZFJXEYCFU
	442950	BD PREWARM HEATER	038290OAEMHDBH32
	442958	BD Viper™ LT System SDA Accessory kit	038290EUNRMZUKKL
	442948	BD Viper LT System software	038290HGAGGXJZL
	441129	BD FOX™ Extraction Tubes	038290OJLDQOTODD

	441994	BD Viper™ SDA Extraction Reagent Trough with Piercing Tool	038290TVUAJVVWRL
	442967	BD Viper™ LT System PCR Accessory Kit	038290KNHKHNPYC2
	442957	BD Viper™ LT System PCR Tube / Tray Kit	038290GHEXZRPED
	442841	BD Viper™ PCR Extraction Reagent Trough with Piercing Tool	038290FTADGENP4M
	441992	BD FOX™ PCR Extraction Tubes	038290ZMTAUZEXRG
	443747	BD Key Card for the BD Viper™ LT System	038290UDTHKMDJEX
Risk Class and Rule:	Catalog Number	Product Trade Name	Risk Class and Rule
	442839	BD Viper™ LT System	Class A, Rule 5 (b)
	442950	BD PREWARM HEATER	
	442958	BD Viper™ LT System SDA Accessory kit	Class A, Rule 5 (a)
	442948	BD Viper LT System software	Class A, Rule 1.4, 5 (b)
	441129	BD FOX™ Extraction Tubes	Class A, Rule 5 (a)
	441994	BD Viper™ SDA Extraction Reagent Trough with Piercing Tool	
	442967	BD Viper™ LT System PCR Accessory Kit	
	442957	BD Viper™ LT System PCR Tube / Tray Kit	

	442841	BD Viper™ PCR Extraction Reagent Trough with Piercing Tool	
	441992	BD FOX™ PCR Extraction Tubes	
	443747	BD Key Card for the BD Viper™ LT System	
	442839	BD Viper™ LT System	
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	442839	BD Viper™ LT System	The BD Viper™ LT System, used in conjunction with appropriate in vitro diagnostic (IVD) assays, is intended for the automated extraction of nucleic acids from multiple specimen types as well as amplification and detection of target nucleic acid sequences by either Strand Displacement Amplification (SDA) or Polymerase Chain Reaction (PCR) technologies.
	442950	BD PREWARM HEATER	The BD Pre-warm heater is intended to pre-warm patient samples according to assay-specific, instrument-defined protocols for use with BD instrument systems.
	442958	BD Viper™ LT System SDA Accessory kit	
	442948	BD Viper LT System software	
	441129	BD FOX™ Extraction Tubes	

	441994	BD Viper™ SDA Extraction Reagent Trough with Piercing Tool	The BD Viper™ LT System, used in conjunction with appropriate in vitro diagnostic (IVD) assays, is intended for the automated extraction of nucleic acids from multiple specimen types as well as amplification and detection of target nucleic acid sequences by either Strand Displacement Amplification (SDA) or Polymerase Chain Reaction (PCR) technologies.
	442967	BD Viper™ LT System PCR Accessory Kit	
	442957	BD Viper™ LT System PCR Tube / Tray Kit	
	442841	BD Viper™ PCR Extraction Reagent Trough with Piercing Tool	
	441992	BD FOX™ PCR Extraction Tubes	
	443747	BD Key Card for the BD Viper™ LT 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):			
<ul style="list-style-type: none">• Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.• Directive 2011/65/EU on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)			

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

**Common Specifications (CS):**


Number:	Title:	Full or Partial Application:

Common Specification have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
442839	BD Viper™ LT System	Class A
442950	BD PREWARM HEATER	Class A
442958	BD Viper™ LT System SDA Accessory kit ^a	Class A
442948	BD Viper LT System software ^a	Class A
441129	BD FOX™ Extraction Tubes ^a	Class A
441994	BD Viper™ SDA Extraction Reagent Trough with Piercing Tool ^a	Class A
442967	BD Viper™ LT System PCR Accessory Kit ^a	Class A
442957	BD Viper™ LT System PCR Tube / Tray Kit ^a	Class A
442841	BD Viper™ PCR Extraction Reagent Trough with Piercing Tool ^a	Class A
441992	BD FOX™ PCR Extraction Tubes ^a	Class A
443747	BD Key Card for the BD Viper™ LT System ^a	Class A

^a Product is not in scope for RoHS Directive 2011/65/EU

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:	<div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:36:40 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change. Updated Conformity Assessment Route, Common specifications table left as blank and formatting changes.