

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	
	443988	BD COR™ PX INSTRUMENT	
	444829	BD COR™ System Software	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	443988	BD COR™ PX INSTRUMENT	038290FKGDTKQB5G
	444829	BD COR™ System Software	038290OZBQYRGANE
Risk Class and Rule :	Catalog Number	Product Trade Name	Risk Class and Rule
	443988	BD COR™ PX INSTRUMENT	Class A, 5 (b)
	444829	BD COR™ System Software	Class A, Rule 1.4 & 5 (b)
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	443988	BD COR™ PX INSTRUMENT	The BD COR™ PX System is to be used for sample-to-result execution and analysis of BD COR™ assays. The PX instrument and associated software will prepare the samples by performing the appropriate pre-analytical processing steps and automatically deliver the samples to the BD COR™ system modules for extraction
	444829	BD COR™ System Software	

			and amplification. The BD COR™ PX system software performs assay analysis to provide qualitative results.
Notified Body:	Not applicable, devices self-certified		
<p>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):</p> <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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
443988	BD COR™ PX Instrument	Class A
444829	BD COR™ System Software ^a	Class A

^aProduct 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 11:27:56 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change. Catalog no., Product trade name column included in risk and rule and in intended purpose section. Updated Conformity Assessment Route, Common specifications table left as blank and formatting changes.