

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA		
<b>Manufacturer SRN:</b>	US-MF-000018910		
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26, Ireland		
<b>Authorised Representative SRN:</b>	IE-AR-000007610		
<b>Product:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	
	443990	BD COR™ GX INSTRUMENT	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	443990	BD COR™ GX INSTRUMENT	038290TFCJEOYLAA
<b>Risk Class and Rule :</b>	Class A, Rule 5 (b)		
<b>Intended Purpose:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Intended Purpose</b>
	443990	BD COR™ GX INSTRUMENT	The BD COR™ GX instrument will perform the assay processing steps of the available molecular tests, including extraction, amplification, and transfer of information to the BD COR system software for analysis and reporting. Available GX tests include the BD Onclarity HPV Assay.
<b>Notified Body:</b>	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"> <li>Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.</li> <li>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)</li> </ul>			

**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
443990	BD COR™ GX INSTRUMENT	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:	<div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022   11:27:43 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 Product, Basic UDI and intended purpose section. Updated Conformity Assessment Route, Common specifications table left as blank and formatting changes.