

## 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> 441991	<b>Product Trade Name</b> BD Onclarity™ HPV Cervical Brush Collection Kit	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b> 441991	<b>Product Trade Name</b> BD Onclarity™ HPV Cervical Brush Collection Kit	<b>Basic UDI-DI</b> 038290MFIZTGUSG6
<b>Risk Class and Rule :</b>	Class A, Rule 5 (c)		
<b>Intended Purpose:</b>	<b>Catalog Number</b> 441991	<b>Product Trade Name</b> BD Onclarity™ HPV Cervical Brush Collection Kit	<b>Intended Purpose</b> The BD Onclarity™ HPV Cervical Brush Collection Kit is intended for the collection and transport of cervical brush specimens to the laboratory for testing with the BD Onclarity™ HPV Assay on the BD Viper™ LT or BD COR™ systems.
<b>Notified Body:</b>	Not applicable, device 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> </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 Specifications have not been issued for this product.

## Devices Covered by this DoC:

SKU#	Device Name	Device Class
441991	BD Onclarity™ HPV Cervical Brush Collection Kit	Class A

Authorised Signatory:	
<b>Name &amp; Title:</b>	Anne Zavertnik, Vice President, Regulatory Affairs
<b>On behalf of:</b>	Becton, Dickinson and Company
<b>Place of Issue:</b>	Sparks, MD, USA
<b>Date of Issue:</b>	10-Nov-2022
<b>Signature:</b>	<div> DocuSigned by:     Signer Name: Anne Zavertnik  Signing Reason: I approve this document  Signing Time: 10-Nov-2022   11:36:32 PM GMT  DC6A638A32E64A8A91F9D8DE330F0415 </div>

**DECLARATION OF CONFORMITY Revision History:**

<b>Version:</b>	<b>Detailed Change Description:</b>
01	Initial Release
02	Changed to template CBI-058 FRM24 (IVDR DoC). Intended purpose, Product and Basic UDI-DI sections changed to table format. Removed "Not available" from common specification table. Updated "On behalf of" with Legal Manufacturer's Name. Minor formatting changes.