



## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, New Jersey 07417-1885 USA
<b>Manufacturer SRN:</b>	US-MF-000019182
<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 Family:</b>	BD Microtainer® Blood Collection Tubes See Pages 2 and 3 for complete list.
<b>Intended Purpose:</b>	See Pages 2 and 3 for complete list.
<b>Risk Class and Rule(s):</b>	Class A (non-sterile), Rule 5c Class A (non-sterile), Rule 5a
<b>Basic UDI-DI:</b>	038290NWQEDLUVKA SKU#(s): 365975, 365964, 365966, 365968, 365979, 365986, 365988, 365993, 363705  038290PGYHYFTA JH – SKU# 368933
<b>Notified Body:</b>	Class A (non-sterile) device. A notified body intervention is excluded as per regulation.
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:

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



**Common Specifications (CS):**

Common Specifications have not been issued for this product.

**Devices Covered by this DoC**

SKU #	Device Name	Risk Class and Rule	Intended Use
363705	BD Microtainer <sup>®</sup> MAP Microtube for Automated Process K2E (1.0 mg) Blood Collection Tubes	Class A (non-sterile) Rule 5c	BD Microtainer <sup>®</sup> Microtube for Automated Process (MAP) Blood Collection Tubes with K <sub>2</sub> EDTA are non-sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, transport, and storage of human capillary blood specimens for in vitro diagnostic testing.  BD Microtainer <sup>®</sup> MAP Blood Collection Tubes with K <sup>2</sup> EDTA are used for testing in hematology and for lead determinations, or for other testing where an EDTA whole blood specimen is required as determined by the laboratory.
365964	BD Microtainer <sup>®</sup> Z (No Additive) Blood Collection Tubes	Class A (non-sterile) Rule 5c	BD Microtainer <sup>®</sup> Blood Collection Tubes are non-sterile, single use in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment and transport of human capillary blood specimens and the subsequent separation of serum or plasma by centrifugation for in vitro diagnostic testing.  BD Microtainer <sup>®</sup> SST <sup>™</sup> , BD Microtainer <sup>®</sup> PST <sup>™</sup> , BD Microtainer <sup>®</sup> Serum, and BD Microtainer <sup>®</sup> Lithium Heparin Blood Collection Tubes are used for testing in chemistry or for other testing where a serum or plasma sample is required as determined by the laboratory.  BD Microtainer <sup>®</sup> Fluoride Blood Collection Tubes are used for glucose determinations or for other tests where a plasma or whole blood sample is required as determined by the laboratory.
365966	BD Microtainer <sup>®</sup> LH Blood Collection Tubes	Class A (non-sterile) Rule 5c	
365968	BD Microtainer <sup>®</sup> SST <sup>™</sup> Blood Collection Tubes	Class A (non-sterile) Rule 5c	
365979	BD Microtainer <sup>®</sup> SST <sup>™</sup> Amber Blood Collection Tubes	Class A (non-sterile) Rule 5c	
365986	BD Microtainer <sup>®</sup> PST <sup>™</sup> LH Blood Collection Tubes	Class A (non-sterile) Rule 5c	
365988	BD Microtainer <sup>®</sup> PST <sup>™</sup> LH Amber Blood Collection Tubes	Class A (non-sterile) Rule 5c	
365993	BD Microtainer <sup>®</sup> FE Blood Collection Tubes	Class A (non-sterile) Rule 5c	



SKU #	Device Name	Risk Class and Rule	Intended Use
365975	BD Microtainer® K2E Blood Collection Tubes	Class A, (non-sterile) Rule 5c	<p>BD Microtainer® Blood Collection Tubes with K<sub>2</sub>EDTA are non-sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, transport, and storage of human capillary blood specimens for in vitro diagnostic testing.</p> <p>BD Microtainer® Blood Collection Tubes with K<sub>2</sub>EDTA are used for testing in hematology and for lead determinations, or for other testing where a whole blood specimen is required as determined by the laboratory.</p>
368933	BD Microtainer® Blood Collection Tube Extender (Accessory)	Class A (non-sterile), Rule 5a	BD Microtainer® Tube Extender is an accessory to BD Microtainer® Blood Collection Tubes. It is a non-sterile, single use, in vitro diagnostic medical device accessory intended to be used by trained healthcare professionals. It fits into the bottom of the tube and increases the tube length to 75mm. With the extender, the tube fits in a standard test tube rack and also provides a larger area for labeling.

**Authorised Signatory:**

<b>Name &amp; Title:</b>	Anne Zavertnik, VP, Regulatory Affairs, Integrated Diagnostic Solutions
<b>Place of Issue:</b>	Franklin Lakes, New Jersey, USA
<b>Date of Issue:</b>	2022-06-22
<b>Signature:</b>	

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release.
02	Administrative corrections - removed template instructions text.