



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	
	445870	BD BACTEC™ MGIT™ 960	
	441743	BD BACTEC™ MGIT™ 320	
	445999	BD BACTEC™ MGIT™ 960 Calibration Vial, (51 pk)	
	445871	BD BACTEC™ MGIT™ 960 Calibration Vial, (17 pk)	
	442942	BD BACTEC™ MGIT™ System Software (USB)	
	445922	BD BACTEC™ MGIT™ System Software (Disk)	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	445870	BD BACTEC™ MGIT™ 960	038290QIKJOYDAEF
	441743	BD BACTEC™ MGIT™ 320	038290BWCHOFNE79
	445999	BD BACTEC™ MGIT™ 960 Calibration Vial, (51 pk)	038290SNRBZXDSMR
	445871	BD BACTEC™ MGIT™ 960 Calibration Vial, (17 pk)	
	442942	BD BACTEC™ MGIT™ System Software (USB)	038290PJNKMHHZZGG



	445922	BD BACTEC™ MGIT™ System Software (Disk)	038290BBLUWABI4B
Risk Class and Rule :	Catalog Number	Product Trade Name	Risk Class and Rule
	445870	BD BACTEC™ MGIT™ 960	Class A, Rule 5(b)
	441743	BD BACTEC™ MGIT™ 320	
	445999	BD BACTEC™ MGIT™ 960 Calibration Vial, (51 pk)	Class A, Rule 1.5 & 5(b)
	445871	BD BACTEC™ MGIT™ 960 Calibration Vial, (17 pk)	
	442942	BD BACTEC™ MGIT™ System Software (USB)	Class A, Rule 1.4 & 5(b)
	445922	BD BACTEC™ MGIT™ System Software (Disk)	
	Catalog Number	Product Trade Name	Intended Purpose
	445870	BD BACTEC™ MGIT™ 960	The BACTEC™ MGIT™ 320/960 System is designed for the automated rapid detection of mycobacteria from clinical specimens (except blood and urine). In addition to detection of mycobacteria, the BD BACTEC MGIT Antimicrobial/Drug Susceptibility Testing
	441743	BD BACTEC™ MGIT™ 320	
	445999	BD BACTEC™ MGIT™ 960 Calibration Vial, (51 pk)	
	445871	BD BACTEC™ MGIT™ 960 Calibration Vial, (17 pk)	



	442942	BD BACTEC™ MGIT™ System Software (USB)	(AST or DST) system is a rapid qualitative procedure for susceptibility testing of Mycobacterium tuberculosis, from culture, to streptomycin, isoniazid, rifampin, ethambutol, and pyrazinamide.
	445922	BD BACTEC™ MGIT™ System Software (Disk)	
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):			
- Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices. - Directive 2011/65/EU as amended (EU) 2015/863 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:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
445870	BD BACTEC™ MGIT™ 960	Class A
441743	BD BACTEC™ MGIT™ 320	Class A
445999	BD BACTEC™ MGIT™ 960 Calibration Vial, (51 pk) ^a	Class A
445871	BD BACTEC™ MGIT™ 960 Calibration Vial, (17 pk) ^a	Class A



442942	BD BACTEC™ MGIT™ System Software (USB) ^a	Class A
445922	BD BACTEC™ MGIT™ System Software (Disk) ^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:	DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:32:26 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Updated to enlarge the signature space.
03	Updated to remove WEEE Directive as it is not a CE-marking regulation. Added footnote to clarify that the RoHS directive applies to the instruments only. Minor formatting changes
04	Revision 04 Template change. Catalog no., Product trade name column included in intended purpose section. Common specifications table left as blank and formatting changes.