

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	
	245115	BD BACTECT™ MGIT™ 960 PZA Medium	
	245119	BD BBL™ MGIT™ AST SIRE Kit	
	245123	BD BACTECT™ MGIT™ 960 SIRE Kit	
	245125	BD BACTECT™ MGIT™ 960 STR 4.0 Kit	
	245126	BD BACTECT™ MGIT™ 960 INH 0.4 Kit	
	245127	BD BACTECT™ MGIT™ 960 EMB 7.5 Kit	
	245128	BD BACTECT™ MGIT™ 960 PZA Kit	
	245157	BD BACTECT™ MGIT™ 960 IR Kit	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	245115	BD BACTECT™ MGIT™ 960 PZA Medium	038290DALPCQIZ34
	245119	BD BBL™ MGIT™ AST SIRE Kit	038290GOJHLDIC79
	245123	BD BACTECT™ MGIT™ 960 SIRE Kit	038290TXRFTDRER2
	245125	BD BACTECT™ MGIT™ 960 STR 4.0 Kit	038290TXRFTDRER2
	245126	BD BACTECT™ MGIT™ 960 INH 0.4 Kit	038290TXRFTDRER2
	245127	BD BACTECT™ MGIT™ 960 EMB 7.5 Kit	038290EZIFCIIC9M
	245128	BD BACTECT™ MGIT™ 960 PZA Kit	038290OPKQGYUDKE

	245157	BD BACTEC™ MGIT™ 960 IR Kit	038290TXRFTDRER2
Risk Class and Rule :	Class C, Rule 3 (k)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	245115	BD BACTEC™ MGIT™ 960 PZA Medium	<ul style="list-style-type: none"> • BD BACTEC MGIT 960 PZA Kit: The BD BACTEC MGIT 960 PZA Kit is a rapid qualitative procedure for susceptibility testing of <i>Mycobacterium tuberculosis</i>, from culture to pyrazinamide (PZA). The BD BACTEC MGIT 960 PZA Kit is used with the automated BD BACTEC MGIT 960 and BD BACTEC MGIT 320 Systems. <p>ADDITIONAL INFORMATION: The BD BACTEC MGIT 960 PZA Kit provides susceptibility test results that may be used to determine the antimicrobial agent of choice in treatment of <i>Mycobacterium tuberculosis</i>.</p> <ul style="list-style-type: none"> • BD BBL MGIT AST SIRE Kit: The BD BBL MGIT AST SIRE System is a rapid manual qualitative procedure for susceptibility testing of <i>Mycobacterium tuberculosis</i>, from culture, to streptomycin, isoniazid, rifampin and ethambutol. The BD BBL MGIT AST SIRE System functions as an aid to diagnosis, providing qualitative susceptibility test results. • BD BACTEC MGIT 960 SIRE Kit • BD BACTEC MGIT 960 STR 4.0 Kit • BD BACTEC MGIT 960 IR Kit • BD BACTEC MGIT 960 INH 0.4 Kit <p>The BD BACTEC MGIT 960 SIRE Kit is a rapid qualitative procedure for susceptibility testing of <i>Mycobacterium tuberculosis</i>, from culture to streptomycin (STR), isoniazid (INH),</p>
	245119	BD BBL™ MGIT™ AST SIRE Kit	
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	245126	BD BACTEC™ MGIT™ 960 INH 0.4 Kit	
	245127	BD BACTEC™ MGIT™ 960 EMB 7.5 Kit	
	245128	BD BACTEC™ MGIT™ 960 PZA Kit	

		<p>rifampin (RIF) and ethambutol (EMB). The BD BACTEC MGIT 960 STR 4.0 Kit and the BD BACTEC MGIT 960 INH 0.4 Kit are for testing at higher drug concentrations. The BD BACTEC MGIT 960 susceptibility test kits are used with the automated BD BACTEC MGIT 960 and BD BACTEC MGIT 320 Systems.</p> <p>ADDITIONAL INFORMATION:</p> <p>The BD BACTEC MGIT 960 susceptibility test kits provide susceptibility test results that may be used to determine the antimicrobial agent of choice in treatment of <i>Mycobacterium tuberculosis</i>.</p> <ul style="list-style-type: none">• BD BACTEC MGIT 960 EMB 7.5 Kit <p>The BD BACTEC™ MGIT™ 960 EMB 7.5 Kit is a rapid qualitative procedure for susceptibility testing of <i>Mycobacterium tuberculosis</i>, from culture, on the automated BD BACTEC™ MGIT™ 960 and BD BACTEC™ MGIT™ 320 Systems, to a high concentration of ethambutol. The BD BACTEC™ MGIT™ 960 EMB 7.5 Kit is used to determine the antimicrobial agent of choice in treatment of <i>Mycobacterium tuberculosis</i> when isolates are resistant to BD BACTEC™ MGIT™ 960 SIRE Kit EMB 5.0.</p>
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
<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 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: N/A
<input checked="" type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: IVDR 750848 EC Certificate Expiration Date: 2027-05-22
<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 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
245115	BD BACTEC™ MGIT™ 960 PZA Medium	Class C
245119	BD BBL™ MGIT™ AST SIRE Kit	Class C
245123	BD BACTEC™ MGIT™ 960 SIRE Kit	Class C
245125	BD BACTEC™ MGIT™ 960 STR 4.0 Kit	Class C
245126	BD BACTEC™ MGIT™ 960 INH 0.4 Kit	Class C
245127	BD BACTEC™ MGIT™ 960 EMB 7.5 Kit	Class C
245128	BD BACTEC™ MGIT™ 960 PZA Kit	Class C
245157	BD BACTEC™ MGIT™ 960 IR Kit	Class C



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:	21-Apr-2023
Signature:	<div>DocuSigned by: </div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release