

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	
	246001	BD Phoenix™ ID Broth	
	246005	BD Phoenix™ Inoculum Broth	
	448012	BD Phoenix™ AP ID Broth	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	246001	BD Phoenix™ ID Broth	038290QPWWQMGKSY
	246005	BD Phoenix™ Inoculum Broth	038290QHLQTGCSG2
	448012	BD Phoenix™ AP ID Broth	038290WODQBNHBGM
Risk Class and Rule:	Class A, Rule 5		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	246001	BD Phoenix™ ID Broth	The BD Phoenix™ Automated Microbiology System is intended for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically significant bacteria. The BD Phoenix System provides rapid results for most aerobic and facultative anaerobic Gram-positive bacteria as well as most aerobic and facultative anaerobic Gram-negative bacteria of human origin. The BD Phoenix System is also intended for the rapid identification of yeast and yeast-like organisms
	246005	BD Phoenix™ Inoculum Broth	
	448012	BD Phoenix™ AP ID Broth	

			Additional Information The BD Phoenix Automated Microbiology System provides qualitative identification and quantitative susceptibility test results using pure culture isolates from patients suspected of having a bacterial, streptococcal, or yeast infection
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): <ul style="list-style-type: none"> Regulation (EU) 2017/746 on <i>In vitro</i> 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 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
246001	BD Phoenix™ ID Broth	Class A
246005	BD Phoenix™ Inoculum Broth	Class A
448012	BD Phoenix™ AP ID Broth	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 11:33:34 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revised to enlarge signature space
03	Revision 04 Template Change. Catalog Number, Product trade name column included in intended purpose section. Additional information was added in Intended purpose. Common specification table left blank. Formatting changes were made.