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
246004	BD Phoenix™ AST Indicator Solution
246006	BD Phoenix™ AP AST Indicator Solution
246009	BD Phoenix™ AST-S Indicator Solution
246015	BD Phoenix™ EMERGE™ AST Indicator Solution

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
246004	BD Phoenix™ AST Indicator Solution	038290VWPGWMYQUP
246006	BD Phoenix™ AP AST Indicator Solution	038290GXYDXFDSL8
246009	BD Phoenix™ AST-S Indicator Solution	038290LXIZYEAHPC
246015	BD Phoenix™ EMERGE™ AST Indicator Solution	038290KPWSRPLKP7

Risk Class and Rule : Class A, Rule 5

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
246004	BD Phoenix™ AST Indicator Solution	
246006	BD Phoenix™ AP AST	

		Indicator Solution	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. **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.
	246009	BD Phoenix™ AST-S Indicator Solution	
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 *In vitro* Diagnostic Medical Devices.

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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
246004	BD Phoenix™ AST Indicator Solution	Class A
246006	BD Phoenix™ AP AST Indicator Solution	Class A
246009	BD Phoenix™ AST-S Indicator Solution	Class A
246015	BD Phoenix™ EMERGE™ AST Indicator Solution	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:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:33:20 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Revision 04 Template Change. Catalog number, Product trade name column included in intended purpose section. Additional information was added in intended purpose section. Common specification table left blank. Formatting changes were made.