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 No.	Product Trade Name
443624	BD Phoenix™ M50 Automated Microbiology System Instrument
441107	BD Phoenix™ Update Data
443866	BD Phoenix™ M50 Automated Microbiology System Application Software

Basic UDI-DI:

Catalog No.	Product Trade Name	Basic UDI-DI
443624	BD Phoenix™ M50 Automated Microbiology System Instrument	038290XCFFNYWADK
441107	BD Phoenix™ Update Data	038290YPCXJKWPPW
443866	BD Phoenix™ M50 Automated Microbiology System Application Software	038290ODACWSAV5Y

Risk Class and Rule :

Catalog No.	Product Trade Name	Risk Class and Rule
443624	BD Phoenix™ M50 Automated Microbiology System Instrument	Class A and Rule 5 (b)
441107	BD Phoenix Update Data	
443866	Phoenix M50 Automated Microbiology System Application Software	

Intended Purpose:

Catalog No.	Product Trade Name	Intended Purpose
443624	BD Phoenix™ M50 Automated Microbiology System Instrument	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
441107	BD Phoenix Update Data	
443866	Phoenix M50 Automated Microbiology System Application Software	

			bacterial, streptococcal, or yeast infection.
Notified Body:	Not applicable, device(s) 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.
- 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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
443624	BD Phoenix™ M50 Automated Microbiology System Instrument	Class A
441107	BD Phoenix™ Update Data *	Class A
443866	Phoenix M50™ Automated Microbiology System Application Software *	Class 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: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:33:43 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Updated to add Manufacturer SRN.
03	Removed WEEE Directive as it is not a CE-marking regulation. Added footnote to clarify that the RoHS directive applies to instruments only. Minor formatting changes.
04	Changed to Rev. 04 Template, Intended Purpose Statement updated, 'Assigned BUDI' changed to Basic UDI-DI, 'Not available' removed from Common Specification table, and statement updated, and legal manufacturer name included in Authorised signatory details