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
440910	BD PhoenixSpec™ Nephelometer
440911	BD PhoenixSpec™ Calibrator Kit
441951	BD PhoenixSpec™ AP Calibrator Kit
441953	BD PhoenixSpec™ Calibrator 2.0 McFarland
441355	BD PhoenixSpec™ Calibrator 0.25 McFarland
441356	BD PhoenixSpec™ Calibrator 0.50 McFarland

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
440910	BD PhoenixSpec™ Nephelometer	038290JFFJQZFU8P
440911	BD PhoenixSpec™ Calibrator Kit	038290JPJAIFED6H
441951	BD PhoenixSpec™ AP Calibrator Kit	038290KQWPIEEVK2
441953	BD PhoenixSpec™ Calibrator 2.0 McFarland	038290LCYOQXQKHT
441355	BD PhoenixSpec™ Calibrator 0.25 McFarland	038290MBBSPWMT9Q
441356	BD PhoenixSpec™ Calibrator 0.50 McFarland	038290MDEHOCIX4R

Risk Class and Rule :	Class A, Rule 5 (b)

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose

	440910	BD PhoenixSpec™ Nephelometer	The BD PhoenixSpec Nephelometer is a portable device designed to measure turbidity of microbial suspensions equivalent to McFarland standards 0.10 to 4.50. The instrument may be used for measurement of inoculum density for the BD BBL™ Crystal™ System and the BD Phoenix™ System. The instrument is battery operated or can be used with an AC adapter.
	440911	BD PhoenixSpec™ Calibrator Kit	
	441951	BD PhoenixSpec™ AP Calibrator Kit	
	441953	BD PhoenixSpec™ Calibrator 2.0 McFarland	
	441355	BD PhoenixSpec™ Calibrator 0.25 McFarland	
	441356	BD PhoenixSpec™ Calibrator 0.50 McFarland	
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.
- 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
440910	BD PhoenixSpec™ Nephelometer	Class A
440911	BD PhoenixSpec™ Calibrator Kit[a]	Class A
441951	BD PhoenixSpec™ AP Calibrator Kit[a]	Class A
441953	BD PhoenixSpec™ Calibrator 2.0 McFarland[a]	Class A
441355	BD PhoenixSpec™ Calibrator 0.25 McFarland[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: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:33:50 PM GMT DC6A638A32F64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 4 Template change. Catalog Number and Product trade name column included in intended purpose section. Corrected classification rule for controls to reflect that they follow the instrument's rule. Common specification table left blank. Formatting changes were made.