BD

Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA Tel: +1.410.316.4000 Fax: +1.410.316.4499
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222
Conformity Assessment Procedure:	-Directive 98/79/EC of the European Parliament and of the Council, Annex III of Directive 98/79/EC -Directive 2011/65/EU of the European Parliament and of the Council as amended by Delegated Directive (EU) 2015/863, Annex II

Product:

REF	Product Name
440910	BD PhoenixSpec™ Nephelometer
440911	BD PhoenixSpec™ Calibrator Kit
441951	BD PhoenixSpec™ AP Calibrator Kit
441953	BD PhoenixSpec™ Calibrator 2.0 McFarland

We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices. This declaration is issued under the sole responsibility of Becton, Dickinson and Company.

Date: July 19, 2024

Name and Authority: Anne Zavertnik
Vice President Regulatory Affairs, IDS

Signature: Anne Zavertnik

Technical File Number: BALTER440910

RECORD REVISION HISTORY TABLE	
Revision	**Description of Changes**
A	Initial Release