

## **Declaration of Conformity**

Manufacturer:	7 Loveton C	yland 21152, USA 316.4000
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	
	REF	Product Name
	240918	BD BBL™ Streptocard™ Enzyme Latex Test Kit
	240917	BD BBL™ Streptocard™ Acid Latex Test Kit
	240922	BD BBL™ Streptocard™ Acid Test Latex B
	240923	BD BBL™ Streptocard™ Acid Test Latex A
	240924	BD BBL™ Streptocard™ Enzyme Extraction
	240925	BD BBL™ Streptocard™ Acid Extraction Reagent
	240928	BD BBL <sup>™</sup> Streptocard <sup>™</sup> Test Cards BD BBL <sup>™</sup> Streptocard <sup>™</sup> Acid Test Latex D
	100000	
	240929	
Product	240935	BD BBL™ Streptocard™ Enzyme Test Latex G
Product:	240935 240936	BD BBL™ Streptocard™ Enzyme Test Latex GBD BBL™ Streptocard™ Enzyme Test Latex F
Product:	240935 240936 240938	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D
Product:	240935 240936 240938 240956	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C
Product:	240935 240936 240938 240956 240957	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C   BD BBL™ Streptocard™ Enzyme Test Latex C
Product:	240935 240936 240938 240956 240957 240958	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C   BD BBL™ Streptocard™ Enzyme Test Latex B   BD BBL™ Streptocard™ Enzyme Test Latex A
Product:	240935 240936 240938 240956 240957 240958 240926	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C   BD BBL™ Streptocard™ Enzyme Test Latex B   BD BBL™ Streptocard™ Enzyme Test Latex A   BD BBL™ Streptocard™ Enzyme Test Latex A   BD BBL™ Streptocard™ Enzyme Test Latex A
Product:	240935 240936 240938 240956 240957 240958 240926 240927	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C   BD BBL™ Streptocard™ Enzyme Test Latex B   BD BBL™ Streptocard™ Enzyme Test Latex A   BD BBL™ Streptocard™ Acid Test Latex C   BD BBL™ Streptocard™ Acid Test Latex C   BD BBL™ Streptocard™ Acid Test Latex C
Product:	240935 240936 240938 240956 240957 240958 240926	BD BBL™ Streptocard™ Enzyme Test Latex G   BD BBL™ Streptocard™ Enzyme Test Latex F   BD BBL™ Streptocard™ Enzyme Test Latex D   BD BBL™ Streptocard™ Enzyme Test Latex C   BD BBL™ Streptocard™ Enzyme Test Latex B   BD BBL™ Streptocard™ Enzyme Test Latex A   BD BBL™ Streptocard™ Enzyme Test Latex A   BD BBL™ Streptocard™ Enzyme Test Latex A

## We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Medical Devices 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: 24-Jan-2022

Name and Authority:

Anne Zavertnik Vice President Regulatory Affairs, IDS

and funtit Signature:

Technical File Number: BALTER240918

RECORD REVISION HISTORY TABLE		
Revision	Description of Changes	
А	Initial Release	