

## Declaration of Conformity

Manufacturer:	7 Loveton C	ryland 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; -Directive 2011/65/EU of the European Parliament and of the Council as amended by Delegated Directive (EU) 2015/863, Annex II	
	REF	Product Name

We hereby declare that the above-mentioned product complies 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 21, 202

Name and Authority:

Anne Zavertnik

WW Vice President Regulatory Affairs, IDS

Signature:

Technical File Number: BALTER440479

RECORD REVISION HISTORY TABLE		
Revision	Description of Changes	
Α	Initial Release in SAP.	