



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
490189	BD FocalPoint™ GS Review Station

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, 2021

Name and Authority: Anne Zavertrnik
WW Vice President Regulatory Affairs, IDS

Signature:

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