




## Declaration of Conformity

<b>Manufacturer:</b>	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA Tel: +1.410.316.4000 Fax: +1.410.316.4499								
<b>Authorized Representative:</b>	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel. : +353.1.202.5222 Fax : +353.1.202.5388								
<b>Conformity Assessment Procedure:</b>	IVD Directive 98/79/EC, of the European Parliament and of the Council, Annex III of Directive 98/79/EC								
<b>Product:</b>	<table border="1"><thead><tr><th>REF</th><th>Product Name</th></tr></thead><tbody><tr><td>256113</td><td>BD Kit for Rapid Detection of SARS-CoV-2 - 1 Pack</td></tr><tr><td>256114</td><td>BD Kit for Rapid Detection of SARS-CoV-2 - 5 Pack</td></tr><tr><td>256091</td><td>BD Kit for Rapid Detection of SARS-CoV-2 - 30 Pack</td></tr></tbody></table>	REF	Product Name	256113	BD Kit for Rapid Detection of SARS-CoV-2 - 1 Pack	256114	BD Kit for Rapid Detection of SARS-CoV-2 - 5 Pack	256091	BD Kit for Rapid Detection of SARS-CoV-2 - 30 Pack
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<b>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.</b>									
<b>Date:</b>	2021-11-11								
<b>Name and Authority:</b>	Anne Zavertnik Vice President Regulatory Affairs, Integrated Diagnostic Solutions								
<b>Signature:</b>									

Technical File Number: BDDSTF256091

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
01	Initial Release
02	Re-issue with BDDSTF256091 updates
03	Re-issue with BDDSTF256091 updates