



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:	<table border="1"><thead><tr><th>REF</th><th>Product Name</th></tr></thead><tbody><tr><td>442296</td><td>BD BACTEC™ FX40</td></tr><tr><td>442299</td><td>Install Kit</td></tr></tbody></table>	REF	Product Name	442296	BD BACTEC™ FX40	442299	Install Kit
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442296	BD BACTEC™ FX40						
442299	Install Kit						
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 21, 2021						
Name and Authority:	Anne Zavertrnik Vice President Regulatory Affairs, IDS						
Signature:							

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
A	Initial Release