



## 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								
<b>Conformity Assessment Procedure:</b>	-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								
<b>Product:</b>	<table><thead><tr><th>REF</th><th>Product Name</th></tr></thead><tbody><tr><td>441385</td><td>BD BACTEC™ FX Top</td></tr><tr><td>441386</td><td>BD BACTEC™ FX Bottom</td></tr><tr><td>441370</td><td>BD BACTEC™ Digital Thermometer</td></tr></tbody></table>	REF	Product Name	441385	BD BACTEC™ FX Top	441386	BD BACTEC™ FX Bottom	441370	BD BACTEC™ Digital Thermometer
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441385	BD BACTEC™ FX Top								
441386	BD BACTEC™ FX Bottom								
441370	BD BACTEC™ Digital Thermometer								
<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>	3 July, 2024								
<b>Name and Authority:</b>	Anne Zavertnik Vice President Regulatory Affairs, IDS								
<b>Signature:</b>									

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
A	Initial Release