

## Declaration of Conformity

Becton Dickinson and Company 7 Loveton Circle Manufacturer: Sparks, Maryland 21152, USA Tel: +1.410.316.4000 Fax: +1.410.316.4499 **Benex Limited** Authorized Pottery Road, Dun Laoghaire Representative: Co. Dublin, Ireland Tel: +353.1.202.5222 -Directive 98/79/EC of the European Parliament and of the Council, Conformity Annex III of Directive 98/79/EC; Assessment -Directive 2011/65/EU of the European Parliament and of the Council Procedure: as amended by Delegated Directive (EU) 2015/863, Annex II REF **Product Name** BD ProbeTec™ ET Lysing Heater Product: 440482

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: 34421, 2021

Name and Authority:

Anne Zavertnik

WW Vice President Regulatory Affairs, IDS

Signature:

Technical File Number: BALTER440482

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