

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

Product:

REF	Product Name
443812	BD MAX™ Extended Enteric Bacterial Panel

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: 17 DEC 2021

Name and Authority:

Anne Zavertnik

WW Vice President Regulatory Affairs, IDS

Signature: In Julia

Technical File Number: <BDDSTF443812>

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
Α	Initial Release in SAP. Transition to current format and indicate Becton, Dickinson and Company (7 Loveton Circle, Sparks, MD) as the Legal Manufacturer.
В	A new specimen collection device (FecalSwab) was validated for use with the BD MAX™ Extended Enteric Bacterial Panel.