

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

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
442963	BD MAX™ 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:

Technical File Number: <BDDSTF442963>

ame Gutte

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
А	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™ Enteric Bacterial Panel.