



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 IV, excluding Sections 4 and 6 Notified Body: BSI Certificate Number: CE 614165						
Product:	<table><tr><th>REF</th><th>Product Name</th></tr><tr><td>443905</td><td>BD CTGC2 for BD MAX™</td></tr><tr><td>443906</td><td>BD CTGCTV2 for BD MAX™</td></tr></table>	REF	Product Name	443905	BD CTGC2 for BD MAX™	443906	BD CTGCTV2 for BD MAX™
REF	Product Name						
443905	BD CTGC2 for BD MAX™						
443906	BD CTGCTV2 for BD MAX™						
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:	19-August-2021						
Name and Authority:	Anne Zavertnik WW Vice President Regulatory Affairs, IDS						
Signature:							

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
A	<ul style="list-style-type: none">- Revised Australian Authorized Representative address- Added VP-9143-03-8066-02, BD MAX CTGCTV2 Specimen Stability, to Section 7 and ERC A5 and B1.1- Added VP-9157-02-8104-01, BD MAX CTGCTV2 Contamination Study, to ERC B1.1, B2.1, and B3.1- Updated Post-Market Surveillance procedures for relevance- Correction of typos and minor format changes throughout- Removed septum caps as components of ref. 443906 and 443905- Inserted eIFU symbol with URL and directions for use to Addendum 1- Removed collected specimen stability at -20°C and added 4 day in-use stability- Updated file locations in ERC- Revised description of contents of BD CTGCTV2 for BD MAX™ System Master Mix (D3), BD CTGCTV2 for BD MAX™ System Unitized Reagent Strip, and BD CTGCTV2 for BD MAX™ System Extraction Tubes (B2) to align with Package Inserts P0242(03) and P0243(02)- Revised reference to Design Transfer Report (Manufacturing Process Transfer for BD CTGCTV2 Products) to Memo re: Manufacturing Process and Transfer for BD MAX CTGCTV2 Products
B	<ul style="list-style-type: none">- Corrected Legal Manufacturer address to Becton Dickinson and Company, 7 Loveton Circle, Sparks, Maryland 21152, USA.