




## Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	442193 - BD BACTEC Plus Anaerobic/F Culture Vials (see Annex A for list of variants) -
<b>We hereby declare that the above mentioned product(s) manufactured after 10/7/2020 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.</b>	
Signed In Baltimore:	10/7/2020
Name and Authority:	Bradford M. Spring , VP, Regulatory Affairs
Signature:	

## **Annex A**

### **BACTEC Glass Mediums** **BD BACTEC Culture Vials in Glass**

**BALTER442193 Ver: A Rev: N/A**

#### **Primary Catalog Number and Product Name:**

442193	BD BACTEC™ Plus Anaerobic/F Culture Vials
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#### **Variants:**

442191	BD BACTEC™ Standard Anaerobic/F Culture Vials
442265	BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials
442194	BD BACTEC™ Peds Plus™ / F Culture Vials
442260	BD BACTEC™ Standard/10 Aerobic/F Culture Vials
442206	BD BACTEC™ Mycosis IC/F Culture Vials
442192	BD BACTEC™ Plus Aerobic/F Culture Vials
442288	BD BACTEC™ Myco/F Lytic Culture Vials
442187	BD BACTEC™ Myco/F-Sputa Medium (50 vials)

Revision date: 21-Feb-2017

Technical File Number: BALTER442193