




## Declaration of Conformity

| <b>Manufacturer:</b>  | Becton Dickinson and Company<br>7 Loveton Circle<br>Sparks, Maryland 21152, USA<br>Tel: +1.410.316.4000<br>Fax: +1.410.316.4499 |     |              |        |                           |
|---|---|-----|--------------|--------|---------------------------|
| <b>Authorized Representative:</b>   | Benex Limited<br>Pottery Road, Dun Laoghaire<br>Co. Dublin, Ireland<br>Tel: +353.1.202.5222                                     |     |              |        |                           |
| <b>Conformity Assessment Procedure:</b>   | Directive 98/79/EC of the European Parliament and of the Council, Annex III of Directive 98/79/EC                               |     |              |        |                           |
| <b>Product:</b>   | <table><tr><th>REF</th><th>Product Name</th></tr><tr><td>441495</td><td>BD BACTEC™ Touch Software</td></tr></table>             | REF | Product Name | 441495 | BD BACTEC™ Touch Software |
| REF   | Product Name  |     |              |        |                           |
| 441495  | BD BACTEC™ Touch Software   |     |              |        |                           |
| <b>We hereby declare that the above mentioned product 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.</b> |   |     |              |        |                           |
| <b>Date:</b> 22 DEC 2021  |   |     |              |        |                           |
| <b>Name and Authority:</b>  |   |     |              |        |                           |
| <b>Signature:</b>    |   |     |              |        |                           |

Technical File Number: BALTER441495

| RECORD REVISION HISTORY TABLE |                        |
|-------------------------------|------------------------|
| Revision                      | Description of Changes |
| A                             | Initial Release        |