



## 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,<br><br>Annex III of Directive 98/79/EC                       |     |              |        |                            |
| <b>Product:</b>  | <table border="1"><tr><td>REF</td><td>Product Name</td></tr><tr><td>274449</td><td>BD Macro-Vue RPR Card Test</td></tr></table> | REF | Product Name | 274449 | BD Macro-Vue RPR Card Test |
| REF  | Product Name  |     |              |        |                            |
| 274449   | BD Macro-Vue RPR Card Test  |     |              |        |                            |
| <b>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.</b> |   |     |              |        |                            |
| <b>Date:</b> 15-October-2021   |   |     |              |        |                            |
| <b>Name and Authority:</b>   | Anne Zavertnik<br>Vice President Regulatory Affairs, IDS  |     |              |        |                            |
| <b>Signature:</b>  |   |     |              |        |                            |

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