



## 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>443419</td><td>BD MAX™ StaphSR</td></tr></table>                       | REF | Product Name | 443419 | BD MAX™ StaphSR |
| REF                                                                                                                                                                                                                                                                                                                  | Product Name                                                                                                                    |     |              |        |                 |
| 443419                                                                                                                                                                                                                                                                                                               | BD MAX™ StaphSR                                                                                                                 |     |              |        |                 |
| <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>                                                                                                                                                                                                                                                                                                         | 2021-04-30                                                                                                                      |     |              |        |                 |
| <b>Name and Authority:</b>                                                                                                                                                                                                                                                                                           | Anne Zavertrnik<br>WW Vice President Regulatory Affairs, IDS                                                                    |     |              |        |                 |
| <b>Signature:</b>                                                                                                                                                                                                                                                                                                    |                                                                                                                                 |     |              |        |                 |

**RECORD REVISION HISTORY TABLE**

| Revision | Description of Changes                                                                                                                                    |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| A        | Initial Release in SAP. Transition to current format and indicate Becton, Dickinson and Company (7 Loveton Circle, Sparks, MD) as the Legal Manufacturer. |