



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 III of Directive 98/79/EC | | | | | | |
| Product: | <table><thead><tr><th>REF</th><th>Product Name</th></tr></thead><tbody><tr><td>240915</td><td>BD BBL™ Staphyloslide™ Latex Test Kit</td></tr><tr><td>240916</td><td>BD BBL™ Staphyloslide™ Latex Test Kit</td></tr></tbody></table> | REF | Product Name | 240915 | BD BBL™ Staphyloslide™ Latex Test Kit | 240916 | BD BBL™ Staphyloslide™ Latex Test Kit |
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| 240915 | BD BBL™ Staphyloslide™ Latex Test Kit | | | | | | |
| 240916 | BD BBL™ Staphyloslide™ Latex Test Kit | | | | | | |
| We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Medical Devices 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: | 24-Jan-2022 | | | | | | |
| Name and Authority: | Anne Zavertnik Vice President Regulatory Affairs, IDS | | | | | | |
| Signature: | | | | | | | |

Technical File Number: BALTER240915

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