



## Declaration of Conformity

<b>Manufacturer:</b>	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA Tel: +1.410.316.4000 Fax: +1.410.316.4499
<b>Authorized Representative:</b>	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland 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>	BD Phoenix™ Gram Negative Panels See Attachment A for Product List
<b>We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Directive 98/79/EC 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>	17 May 2021
<b>Name and Authority:</b>	Anne Zavertnik Vice President Regulatory Affairs, IDS
<b>Signature:</b>	A handwritten signature in black ink, appearing to read "Anne Zavertnik", is written over a white background.

Technical File Number: BALTERPHXGRAMNEG

**Attachment A: Product List**

<b>Catalog Number</b>	<b>Panel Name</b>
448007	BD Phoenix™ NID
448103	BD Phoenix™ NMIC/ID-76
448286	BD Phoenix™ NMIC-84
448397	BD Phoenix™ NMIC/ID-92
448443	BD Phoenix™ NMIC/ID-414
448445	BD Phoenix™ UNMIC/ID-416
448446	BD Phoenix™ UNMIC-416
448505	BD Phoenix™ NMIC/ID-4
448612	BD Phoenix™ NMIC-411
448615	BD Phoenix™ NMIC/ID-411
448620	BD Phoenix™ NMIC/ID-415
448739	BD Phoenix™ NMIC/ID-208
448740	BD Phoenix™ NMIC-207
448746	BD Phoenix™ NMIC/ID-400
448747	BD Phoenix™ NMIC/ID-405
448748	BD Phoenix™ NMIC/ID-406
448749	BD Phoenix™ UNMIC/ID-407
448764	BD Phoenix™ NMIC-203
448781	BD Phoenix™ NMIC/ID-94
448783	BD Phoenix™ NMIC/ID-95
448788	BD Phoenix™ NMIC-404
448790	BD Phoenix™ UNMIC/ID-401
448792	BD Phoenix™ NMIC-400
448794	BD Phoenix™ NMIC/ID-402
448804	BD Phoenix™ UNMIC-409
448805	BD Phoenix™ UNMIC/ID-409
448839	BD Phoenix™ NMIC/ID-99
448869	BD Phoenix™ NMIC-406
448873	BD Phoenix™ UNMIC/ID-403
448874	BD Phoenix™ NMIC-402
448875	BD Phoenix™ UNMIC-401
448876	BD Phoenix™ UNMIC-403
448877	BD Phoenix™ NMIC-408
448878	BD Phoenix™ NMIC/ID-408
448879	BD Phoenix™ UNMIC-407
448935	BD Phoenix™ NMIC/ID-55
449001	BD Phoenix™ NMIC-417
449012	BD Phoenix™ NMIC/ID-418
449023	BD Phoenix™ NMIC-500
449025	BD Phoenix™ NMIC-502
449026	BD Phoenix™ NMIC/ID-503
449027	BD Phoenix™ NMIC/ID-504
449040	BD Phoenix™ NMIC/ID-431
449041	BD Phoenix™ NMIC-501
449042	BD Phoenix™ NMIC-431
449044	BD Phoenix™ NMIC/ID-435
449045	BD Phoenix™ NMIC/ID-433
449046	BD Phoenix™ NMIC-433

<b>Catalog Number</b>	<b>Panel Name</b>
449047	BD Phoenix™ NMIC/ID-421
449049	BD Phoenix™ NMIC-450
449050	BD Phoenix™ NMIC-442
449051	BD Phoenix™ NMIC/ID-441
449052	BD Phoenix™ UNMIC-432
449053	BD Phoenix™ UNMIC/ID-432
449054	BD Phoenix™ NMIC-440
449056	BD Phoenix™ NMIC-505
449058	BD Phoenix™ NMIC/ID-442
449062	BD Phoenix™ NMIC-422
449472	BD Phoenix™ NMIC-451
449485	BD Phoenix™ NMIC-472
449562	BD Phoenix™ NMIC-473
449580	BD Phoenix™ UNMIC/ID-471
449600	BD Phoenix™ UNMIC-471
449723	BD Phoenix™ NMIC-470
449724	BD Phoenix™ NMIC/ID-470
449727	BD Phoenix™ NMIC-474
449728	BD Phoenix™ NMIC-475

<b>RECORD REVISION HISTORY TABLE</b>	
<b>Revision</b>	<b>Description of Changes</b>
A	Initial Release using new template.
B	Added new panel catalog numbers 449727 and 449728 per CC_2021_02657.