



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:	BD Phoenix™ Gram Negative Panels See Attachment A for Product List
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.	
Date:	17 May 2021
Name and Authority:	Anne Zavertnik Vice President Regulatory Affairs, IDS
Signature:	A handwritten signature in black ink, appearing to read "Anne Zavertnik", written over a light blue horizontal line.

Technical File Number: BALTERPHXGRAMNEG

Attachment A: Product List

Catalog Number	Panel Name
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

Catalog Number	Panel Name
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

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