

Declaration of Conformity

Becton Dickinson and Company

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Benex Limited Authorized

Pottery Road, Dun Laoghaire Representative:

REF

222321

222531

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Conformity **Assessment** Procedure:

Directive 98/79/EC of the European Parliament and of the

Council, Annex III of Directive 98/79/EC

Product Name

W135, 1 mL

222321	Contains Group A, B, C, D, 1 mL
229101	Difco Neisseria Meningiditis Antiserum Poly 2. Contains Group X, Y, Z, 1 mL
222281	Difco Neisseria Meningiditis Antiserum Group A, 1 mL
222291	Difco Neisseria Meningiditis Antiserum Group B, 1 mL
222301	Difco Neisseria Meningiditis Antiserum Group C, 1 mL
222311	Difco Neisseria Meningiditis Antiserum Group D, 1 mL
228801	Difco Neisseria Meningiditis Antiserum Group X, 1 mL
228811	Difco Neisseria Meningiditis Antiserum Group Y, 1 mL
228911	Difco Neisseria Meningiditis Antiserum Group Z, 1 mL
222521	Difco Neisseria Meningiditis Antiserum Group Z', Prime 1 mL
222531	Difco Neisseria Meningiditis Antiserum Group

Difco Neisseria Meningiditis Antiserum Poly.

Product:

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: 07-Feb-2022

Name and Authority: Anne Zavertnik

Vice President Regulatory Affairs, IDS

Signature: The Juth

Technical File Number: BALTER222321

RECORD REVISION HISTORY TABLE	
Revision	Description of Changes
A	Initial Release