

Manufacturer: Becton, Dickinson and Company

7 Loveton Circle

Sparks, MD 21152 USA

Authorized Benex Limited

Representative: Pottery Road, Dun Laoghaire

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Conformity Annex III of the IVD Directive 98/79/EC. assessment

Product: 229701 - VIAL E COLI O ANTISERUM O157 SEROL TEST

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We hereby declare that the above mentioned product(s) manufactured after 2013/03/26 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/03/26
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bodled M Sty

Technical File Number: ER229701

procedure: