

Manufacturer: Becton, Dickinson and Company

7 Loveton Circle

Sparks, MD 21152 USA

Authorized Benex Limited Representative: Rineanna House

Shannon Free Zone Shannon, County Clare

Ireland

Tel: 353-61-47-29-20 / Fax: 353-61-47-29-07

Conformity assessment procedure:

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

Product: 441362 - Urine Preservative Transport for the BD ProbeTec Qx Amplified DNA

Assays

441359 - P-Caps

441360 - Specimen Tubes and P-Caps

We hereby declare that the above mentioned product(s) manufactured after 2013/02/06 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.

Signed In Baltimore:	2013/02/06
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	Bodled M Sig

Technical File Number: ER441362