

DECLARATION OF CONFORMITY CERTIFICATE

MANUFACTURER: UNIPATH LTD.
PRIORY BUSINESS PARK
BEDFORD
MK44 3UP

PRODUCT: Determine HIV-1/2
Product Codes: 7D2346 & 7D2347

NOTIFIED BODY: Lloyd's Register Quality Assurance Limited
Hiramford
Middlemarch Office Village
Siskin Drive
Coventry, CV34FJ

NB ID NUMBER: 0088

CLASSIFICATION: Annex II List A

We herewith declare that the above mentioned product meets the provisions of the Council Directive 98/79/EC for *in vitro* diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

The object of the Declaration described above is in conformity with the requirements of the following documents:

Document No.	Title
BS EN 375: 2001	Graphical Systems for Use in the Labelling of Medical Devices
BS EN 980: 2003	Graphical symbols for use in the labelling of Medical Devices.
BS EN ISO 9001: 2000	Quality System – Model for Quality Assurance in Design, Development, Production, Installation and Servicing.
BS EN ISO 13485: 2003	Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes.
BS EN ISO 14971: 2001	Medical Devices. Application of Risk Management to Medical Devices.
BS EN 13640: 2002	Stability Testing of In Vitro Diagnostic Reagents
BS EN 13641: 2002	Elimination or Reduction of Risk of Infection Related to In Vitro Diagnostic Reagents
EN ISO/IEC 17050-1:2004	Conformity assessment–Supplier's declaration of conformity–Part 1: General requirements.

SIGNED FOR AND ON BEHALF OF: UNIPATH LTD

PLACE, DATE OF ISSUE: BEDFORD, 2007/08/29

L. Moore
Lesley Moore, Regulatory Affairs Manager

2007 08 29
Date