Cepheid

CE DECLARATION OF CONFORMITY

Manufacturer:
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189
USA

Authorized Representative:
Cepheid Europe S.A.S.
81470 Maurens-Scopont
France

Cepheid's Xpert Factor II & Factor V (Catalogue number **GXFIIFV-10**) has been tested to the requirements for the following directives and standards. We, the undersigned, hereby declare that the product specified above conforms to the stated directives and standards.

Application of Council Directives, 98/79/EC of the European Parliament and the Council 27 October 1998 on *in-vitro* medical devices (IVD) in accordance with Annex I and Annex III.

In addition, the above stated product has been manufactured under a certified Quality System compliant with the following standards:

ISO 13485:2003: The design, development, manufacture, and service of nucleic acid detection systems including analyzers, reagents, and test kits.
ISO 14971 Application of Risk Management to Medical Devices.
EN 13640 Stability Testing of In-Vitro Diagnostic Reagents.
EN 980 / ISO 15223-1 Symbols for Use in the Labeling of Medical Devices.

Signature

7/24/2013
Date

Kerry Flom, Ph.D.
Executive Vice President and Chief Regulatory Officer