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

Xpert EV (Catalogue number GXEV-100N-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;
EN ISO 13485:2012: The design, development, manufacture, and service of nucleic acid detecttion systems including analyzers, reagents, and test kits.
EN ISO 14971:2012 Application of Risk Management to Medical Devices
EN ISO 13640 Stability Testing of In-Vitro Diagnostic Reagents
EN 980 / ISO 15223-1 Symbols for use in the Labeling of Medical Devices

Signature Date 02/25/14

Nicholas Vavlas,
Vice President of Regulatory Submissions