



CE DECLARATION OF CONFORMITY

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

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

The Cepheid's GeneXpert[®] System (A PCR Thermal Cycler Instrument) model numbers

GX-I, GX-II, GX-IV and GX-XVI

GX-I R2, GX-II R2, GX-IV R2, GX-XVI R2, and GXCAL-CE-5

GeneXpert[®] Infinity-48 System

GeneXpert[®] Infinity-48s System

GeneXpert[®] Infinity-80 System

have been tested to the requirements for the following directives and standards. We, the undersigned, hereby declare that the equipment specified above conforms to the stated directives and standards as applicable.

IVD In-Vitro Device Directive 98/79/EC

EMC directive 2004/108/EC

LVD 2006/95/EC

WEEE Directive 2002/96/EC

In addition, the above stated product has been manufactured under a certified Quality System compliant with the following standards, granted by Cepheid's Notified Body, Underwriters laboratories, Inc.

ISO 13485:2003, CAN/CSA EN ISO 13485:2003 and EN ISO 13485:2003

Signature

3rd December 2012

Date

Russel K. Enns, Ph.D.
Senior Vice President and Chief Regulatory Officer