Cepheid.

CE DECLARATION OF CONFORMITY

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

European Representative
Cepheid Europe S.A.
81470 Maures_Scopont
France

The Cepheid's GeneXpert ® Diagnostic (A PCR Thermal Cycler instrument) model numbers **GX-I, GXIV, and GX-XVI** 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.

IVD In-Vitro Device Directive 98/79/EC
EMC Directive, 89/336/EEC
EN 61326:1997 with A1:1998, A2:2001 and A3:2003 "*Electrical Equipment for Measurement and Control and Laboratory Use – EMC Requirements*"
Reference Report File number R57753, Elliott Labs. Inc.
EN 55022 Class A Radiated Emissions
EN 55022 Class A Conducted Emissions
EN 61000-4-2 Electrostatic Discharge Immunity
EN 61000-4-3 Radiated, Radio Frequency, Electromagnetic Field Immunity
EN 61000-4-4 Electrical Fast Transient / Burst Immunity
EN 61000-4-5 Surge Immunity
EN 61000-4-6 Immunity to Conducted Disturbances, Induced by RF Fields
EN 61000-4-11 Immunity to Voltage Dips, Interruptions, and Variations
EN 61000-3-2 Harmonic Current Emissions
EN 61000-3-3 Voltage Fluctuations and Flicker
LVD 73/23/EEC
Reference Reports 30382892.001, 30382892.004 TUV Rheinland
EN 61010-1:2001 2nd Edition, *Electrical Safety for Lab Test and Measurement Equipment*
EN 61010-2:101:2002 2nd Edition, *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Particular Requirements for IVD Medical Equipment.*
UL 61010-1 2nd Edition:2004
CAN-CSA 22.2 No. 61010 2nd Edition:2004
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, CEN EN ISO 13485:2003 and EN ISO 13485:2003

Russel K Enns 12-20-2007

Signature Date

Russel K. Enns, Ph.D.
Senior Vice President Regulatory and Clinical Affairs, Quality Systems and Reimbursements