Cepheid.

CE DECLARATION OF CONFORMITY

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

Authorized Representative
Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Cepheid's GeneXpert® Instrument Systems (A PCR Thermal Cycler Instrument) with model numbers:

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

GX-I R2, GX-II R2, GX-IV R2, GX-XVI R2

GeneXpert® Infinity-48 System

GeneXpert® Infinity-48s System

GeneXpert® Infinity-80 System

Digitally signed by Anghel Gabriela-Cristina
Date: 2021.01.25 12:22:21 EET
Reason: MoldSign Signature
Location: Moldova

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. 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.

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998
- ISO 15223-1 Symbols for Use in the Labeling of Medical Devices
- EN 14971: 2012 Application of Risk Management to Medical Devices
- Electromagnetic Compatibility Directive 2004/108/EC
- EN 61326-2-6: Electrical equipment for measurement, control laboratory use –EMC requirements- Part 2-6; Particular requirements – In-vitro diagnostic (IVD) medical equipment
- EN 61010-1:2001 2nd Edition (Electrical Safety for Lab Test and Measurement Equipment)
- EN 61010-2:101; 2015 2nd Edition Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Particular Requirements for IVD Medical Equipment.
- EN 50103: Guidance on the Application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the Active Medical Device Industry
- EN ISO 18113-3:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use

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- IEC 60825 – Safety of Laser Products (for use of UV LEDs)
- Low Voltage Directive 2006/95/EC;
- Energy Labeling Directive 2010/30/EU
- RoHS Directive 2011/65/EC
- Machinery Directive 2006/42/EC
- Packaging and Packaging Waste Directive 2006/62/EC; and
- Waste Electrical & Electronic Equipment (WEEE) Directive 2002/96/EC

Xpert Calibration (catalogue number **GXCAL-CE-5**) and Xpert Check (catalogue number **XPERTCHECK-CE-5)** have been tested to the requirements for the following directives and standards. We, the undersigned, hereby declare that the products specified above conform 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.

- IVD In-Vitro Device Directive 98/79/EC
- ISO 15223-1 Symbols for Use in the Labeling of Medical Devices
- EN 14971: 2012 Application of Risk Management to Medical Devices
- EN ISO 13640: 2002 Stability Testing of In-Vitro Diagnostic Reagents
- EN ISO 18113-2:2011 In vitro Diagnostic medical devices-Information supplied by the manufacturer (labeling) Part 2

In addition, the above stated products have been manufactured under a certified Quality System compliant with the following standards, granted by Cepheid's Notified Body, LRQA.

- EN ISO 13485: 2012- Quality Management System Requirements for Regulatory Purposes.
- CAN/CSA EN ISO 13485: 2003- Quality Management System Requirements for Regulatory Purposes.

J F Kelly

Signature
Jim Kelly, Ph.D.
Executive Director Regulatory Affairs

9-28-2016

Date