Cepheid

CE DECLARATION OF CONFORMITY

Manufacturer:
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

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

Xpert Bladder Cancer Monitor (catalogue number GXBLAD-CM-CE-10) has been tested to the requirements for the following directives and standards. The undersigned hereby declares 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 detection 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

ISO 15223-1 Symbols for Use in the Labeling of Medical Devices

EN ISO 18113-2 In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) Part 2

J P Kelly — Signature

9-2-2016 — Date

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