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 Xpress Strep A (catalogue number XPRSTREPA-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 Medical devices - Quality management systems - Requirements for regulatory purposes.

EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 23640:2015 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents

ISO 15223-1 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.

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

Joseph D Whitmore
Signature

10/06/2017
Date

Joseph Whitmore
Senior Director, International Clinical and Regulatory Affairs