Cepheid®

CE DECLARATION OF CONFORMITY

Manufacturer:
Cepheid
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Sunnyvale, CA 94089
USA

European Representative:
Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Xpert Vaginal/Endocervical Specimen Collection Kit (catalogue number SWAB/A-50),
Xpert Urine Specimen Collection Kit (catalogue number URINE/A-50), and
Xpert Swab Specimen Collection Kit (catalogue number SWAB/G-50)

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 of 27 October 1998 on *in-vitro* medical devices (IVD) in accordance with Annex III and Annex I.

In addition, the above stated products have been manufactured under a certified Quality System compliant with the following standards:

EN ISO 13485:2012 Quality Management System Requirements for Regulatory Purposes.

EN ISO 14971:2012 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.

ISO 10993-7:2008 Biological evaluation of medical devices -Part 7: Ethylene oxide sterilization residuals

EN ISO 11135-1: 2007 Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11737-2: 2009 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Soumya Akunkumar

25 June 2019
Date