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 BCR-ABL Ultra (catalogue number **GXBCRABL-10**) has been tested to the requirements for the following directives and standards. We, the undersigned, hereby declare 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 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 17511:2003	In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.
EN ISO 18113:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) Parts 1-3

Ronald Douglas Dunn

Signature

12 NOV. 2019

Date

Ronald D. Dunn
Vice President, Global Regulatory Affairs