**CE DECLARATION OF CONFORMITY**

**Manufacturer:**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

**Authorized Representative:**
Cepheid Europe S.A.S.
Vira Soleil
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.


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 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
- 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

[Signature]
Ronald D. Dunn
Vice President, Global Regulatory Affairs

Date
12 Nov. 2019