EC 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

Product name: Xpert® BCR-ABL Ultra
Catalogue number(s): GXBCRABL-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD).

Product classification: General IVD (self-declared)
Conformity Assessment route: Annex III, self-declared

Signed on behalf of Cepheid by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

June 5, 2024
Date of Issue

Place of Issue: Bromma, Sweden

*This Declaration of Conformity (DoC) has been issued due to the addition of an additional manufacturing site. This update does not impact the design or intended use of the device, hence the update made is not deemed a significant change according to MDCG 2022-6 and are allowable under the IVDR (EU) 2017/746 Article 110(3) Transitional Provisions as amended by Regulation (EU) 2022/112. The preceding DoC for the device was issued on May 13, 2022 and should be used in conjunction with this DoC.