



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 p190
Catalogue number(s): GXBCRABLP190-CE-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:

Suzette Chance
Signature
Suzette Chance, PhD
Sr. Director Regulatory Affairs

May 11, 2023
Date of Issue

Place of Issue: Sunnyvale, California, USA