



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-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:

Signature

Lena Kirsell

Senior Manager of Regulatory Affairs

Date of Issue

Place of Issue: Solna, Sweden