

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® NPM1 Mutation **Catalogue number(s)**: GXNPM1-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 (Dec 23, 2023 15:44 P

Signature

Suzette Chance, PhD.

VP Regulatory Affairs – NPD, Cepheid

Place of Issue: Sunnyvale, California, USA

Dec 23, 2023

Date of Issue