

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® Xpress Strep A

Catalogue number(s): XPRSTREPA-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 Kirsel

Senior Manager of Regulatory Affairs

Place of Issue: Solna, Sweden

May 24, 202 Date of Issue