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® GBS
Catalogue number(s): GXGBS-100N-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 Digitally signed by Lena Kirsel Date: 2024.02.13 09:28:18 +01'00'

February 13, 2024
Date of Issue

Lena Kirsel
Senior Manager Regulatory Affairs

Place of Issue: Solna, Sweden

*This Declaration of Conformity (DoC) has been issued due to the addition of a 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 is 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 24, 2022 and should be used in conjunction with this DoC.