Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® Xpress GBS
Catalogue number(s): XPRSGBS-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), (LVFS 2001:7).

Product classification: General IVD (self-declared)
Conformity Assessment route: Annex III, self-declared

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

November 25, 2022
Date of Issue*

Place of Issue: Solna, Sweden

*This Declaration of Conformity (DoC) has been issued due to updates made to the analytical performance report for the device. The updates made do not impact the design, intended use, performance claims or introduce any additional risks to the device, hence the updates made are not deemed significant change according to MDCG 2022-6 and are allowable under the IVDR (EU) 2017/746 Article 110(3) Transitional Provisions as amended by Regulation (EU) 2022/112. The initial DoC for the device was issued on May 13, 2022 and should be used in conjunction with this DoC.

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Signed on behalf of Cepheid AB by:

Suzette Chance
Signature
Suzette Chance
Senior Director, Regulatory Affairs

13 May 2022
Date of Issue

Place of Issue: Sunnyvale, USA