EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® MRSA/SA Blood Culture
Catalogue number(s): GXMRSA/SABC-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:

Lena Kirsel

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

September 28, 2023
Date of Issue

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 23, 2022 and should be used in conjunction with this DoC.