

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB Röntgenvägen 5 SE-171 54 Solna

Sweden

Product name:

Xpert® MRSA/SA SSTI

Catalogue number(s):

GXMRSA/SA-SSTI-CE

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

Place of Issue: Solna, Sweden

May 23,2022
Date of Issue