EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® MTB/RIF Ultra
Catalogue number(s): GXMTB/RIF-ULTRA-10
GXMTB/RIF-ULTRA-50

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:

Davide Mantega

Signature
Davide Mantega
Senior Manager Regulatory Affairs

28th February 2024
Date of Issue

Place of Issue: Mâcon, France

*This Declaration of Conformity (DoC) has been issued following updates to the Instructions for Use. These changes were made to be compliant with the information presented in the clinical and reproducibility reports and the Design Input Requirements. A limitation has also been added. 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.