

Declaration of Conformity

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna, Sweden

declare under our sole responsibility that the product

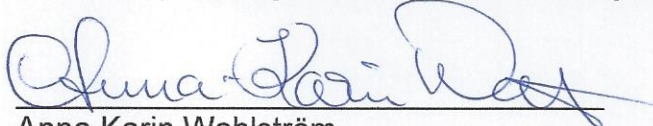
Xpert® MTB/RIF Ultra

Ref. No GXMTB/RIF - ULTRA -10

GXMTB/RIF - ULTRA - 50

to which this declaration relates is developed and manufactured in conformity with the requirements of Full Quality Assurance in the Directive 98/79/EC Annex III (LVFS 2001:7) and that the product is in conformity with the Essential Requirements of the Directive 98/79/EC Annex I (LVFS 2001:7).

In addition the above stated product have been developed and manufactured under a Quality Management system in compliance to ISO 13485:2003.



Anna Karin Wahlström
acting Director, Quality Assurance

20170416

Date

Scope of the CE label:

Xpert® MTB/RIF Ultra performed in the GeneXpert® DX System or GeneXpert® InfinitySystems

