

Declaration of Conformity

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna, Sweden

declare under our sole responsibility that the product

Xpert[®] Ebola

Ref. No GXEBOLA-CE-10
GXEBOLA-CE-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.



Molly Verner
Deputy Managing Director

20150731

Date

Scope of the CE label:
Xpert[®] Ebola performed on the GeneXpert[®] Instrument Systems.