

# Declaration of Conformity

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna, Sweden

declare under our sole responsibility that the product

**Xpert<sup>®</sup> HCV VL Fingerstick**

Ref. No GXHCV-FS-CE-10

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 IV (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) and Annex II.

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



Lena Kirsell  
Regulatory Affairs Manager

March 29, 2018

Date

**Scope of the CE label:**

Xpert<sup>®</sup> HCV VL Fingerstick performed in the GeneXpert<sup>®</sup> DX System or GeneXpert<sup>®</sup> Infinity Systems