

Declaration of Conformity

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna, Sweden

declare under our sole responsibility that the product

Xpert[®] HBV Viral Load

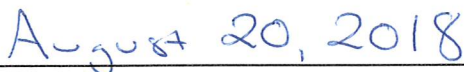
Ref. No. GXHBV-VL-CE-10

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 13485:2016.



Lena Kirsell
Regulatory Affairs Manager



Date

Scope of the CE label:

Xpert[®] HBV Viral Load performed in the GeneXpert[®] DX System or GeneXpert[®] Infinity Systems