

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HCV VL Fingerstick
Catalogue number(s): GXHCV-FS-CE-10

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: Annex II, list A

Conformity Assessment route: Annex IV

Notified Body: BSI Group The Netherlands B.V.

Say Building, John M. Keynesplein 9

1066 EP Amsterdam

The Netherlands

Notified Body number: 2797

EC Certificate – Full Quality Assurance: CE 708525

EC Design-Examination Certificate: CE 708531

Signed on behalf of Cepheid AB by:



Signature

Lena Kirsal

Senior Manager of Regulatory Affairs



Date of Issue

Place of Issue: Solna, Sweden