



EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HBV Viral Load
Catalogue number(s): GXHBV-VL-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 708526

Signed on behalf of Cepheid AB by:

Signature

Lena Kirsal

Senior Manager of Regulatory Affairs

Date of Issue

Place of Issue: Solna, Sweden