EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV Section 4

No. **CE 708531**

Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

In respect of:

Xpert HCV VL Fingerstick

on the basis of our examination of the design dossier relating to the device under the requirements of Council Directive 98/79/EC, Annex IV Section 4, the design of the device conforms to the requirements of 98/79/EC.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2019-03-28** Date: **2022-04-27** Expiry Date: **2025-05-26**

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHCV-FS-CE-10	Xpert HCV VL Fingerstick	N/A	In vitro reverse transcription polymerase chain reaction (RT-PCR) assay for the detection and quantification of Hepatitis C virus (HCV) RNA in human capillary fingerstick EDTA whole blood and venous EDTA whole blood from HCV infected individuals using the automated GeneXpert Instrument systems.	Annex II list A

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Certificate History

Date	Reference Number	Action
28 March 2019	9738797	First issue. Transfer from another Notified Body.
09 August 2019	3057083	Change: extension of shelf life to 12 months.
14 May 2021	3411741	Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2.
Current	3616228	Renewal.

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