

EC Design-Examination Certificate

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

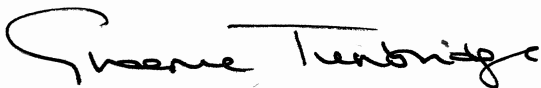
No. **CE 708531**
Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

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**

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 708531

Issued To:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

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

First Issued: **2019-03-28**

Date: **2022-04-27**

Expiry Date: **2025-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 708531

Issued To:

**Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden**

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.

First Issued: **2019-03-28**

Date: **2022-04-27**

Expiry Date: **2025-05-26**

...making excellence a habit.™

Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.