EC Design-Examination Certificate

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

No. **CE 708527**

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

In respect of:

Xpert HCV Viral Load

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: **2022-03-25** Expiry Date: **2025-03-08**

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Supplementary Information to CE 708527

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHCV-VL-CE-10; GXHCV-VL-IN-10	Xpert HCV Viral Load	N/A	In vitro diagnostic test performed on GeneXpert Instrument Systems for the rapid quantitation of Hepatitis C Virus (HCV) RNA in human serum or plasma (EDTA) from HCV infected individuals	Annex II list A

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Certificate History

Date	Reference Number	Action
28 March 2019	9738795	First issue. Transfer from another Notified Body.
09 August 2019	3057082	Change: extension of shelf life to 18 months.
09 March 2020	3145535	Renewal.
25 February 2021	3289905	Change: intended use update; addition of seroconversion panels in the performance claim; diagnostic specificity data update.
14 May 2021	3411679	Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2.
Current	3643376	Change of IVDD expiry date according to Regulation (EU) 2022/112.

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