EC Design-Examination Certificate

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

No. **CE 708526**

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

In respect of:

Xpert HBV 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: **2022-04-22** Expiry Date: **2025-05-26**

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Supplementary Information to CE 708526

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHBV-VL-CE-10	Xpert HBV Viral Load	N/A	In vitro nucleic acid amplification test designed for the quantitation of Hepatitis B Virus (HBV) DNA in human serum or plasma (EDTA) from chronically HBV-infected individuals using the automated GeneXpert Systems.	Annex II list A

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Certificate History

Date	Reference Number	Action
28 March 2019	9738793	First issue. Transfer from another Notified Body.
09 August 2019	3057081	Change: Extension of shelf life to 12 months.
28 August 2020	3277769	Extension to shelf life claim from 12 months to 18 months
14 May 2021	3411740	Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2.
Current	3615745	Renewal.

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