

EC Design-Examination Certificate

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

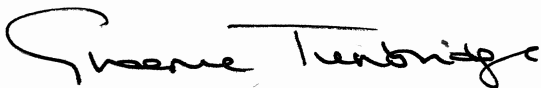
No. **CE 708526**
Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

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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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.

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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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