

# EC Design-Examination Certificate

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

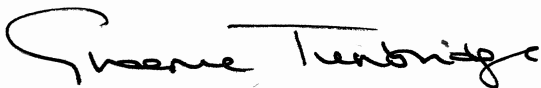
**No.** **CE 708535**  
Issued To: **Cepheid AB**  
**Röntgenvägen 5**  
**SE-171 54 Solna**  
**Sweden**

In respect of:

**Xpert HIV-1 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: **2022-04-08**

Expiry Date: **2024-12-18**

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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 708535

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHIV-VL-CE-10; GXHIV-VL-IN-10 GXHIV-VL-CN-10	Xpert HIV-1 Viral Load	N/A	In vitro reverse transcriptase polymerase chain reaction (RT-PCR) assay for the detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) RNA in human plasma from HIV-1 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	9738821	First issue. Transfer from another Notified Body.
20 September 2019	3069238	Addition of Xpert HIV-1 Viral Load GXHIV-VL-CN-10 to the product range.
27 November 2019	3079016	Renewal.
20 April 2021	3411675	Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2.
Current	3643375	Change of IVDD expiry date according to Regulation (EU) 2022/112.

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