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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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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