EC Design-Examination Certificate

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

No. **CE 731750**

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

In respect of:

Xpert HIV-1 Viral Load XC

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: **2021-04-16** Date: **2022-05-20** Expiry Date: **2025-05-26**

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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 731750

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHIV-VL-XC-CE-10	Xpert HIV-1 Viral Load XC	N/A	In vitro reverse transcription polymerase chain reaction (RT-PCR) test for the quantification of human immunodeficiency virus type 1 (HIV-1) RNA in human EDTA plasma using the automated GeneXpert® System.	Annex II List A

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Certificate History

Date	Reference Number	Action
16 April 2021	3251975	First Issue.
23 March 2022	3643374	Change of IVDD expiry date according to Regulation (EU) 2022/112.
Current	3483460	Amendment – update to device's intended use statement to include its use in near patient testing environments, change of some of the assay component concentrations, update to assay definition file and correction to error in IFU – Analytical specificity (exclusivity) section.

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