EC Design-Examination Certificate

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

No. **CE 742686**

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

In respect of:

Xpert HIV-1 Qual 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: **2021-06-24** Date: **2022-04-27** Expiry Date: **2025-05-26**

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Supplementary Information to CE 742686

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHIV-QA-XC-CE-10	Xpert HIV-1 Qual XC	N/A	Qualitative in vitro diagnostic test to detect Human Immunodeficiency Virus Type 1 (HIV-1) total nucleic acids on the automated GeneXpert System using human whole blood and dried blood spots from individuals suspected of HIV-1 infection.	Annex II, List A

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Certificate History

Date	Reference Number	Action
24 June 2021	3368365	First Issue.
23 March 2022	3643373	Change of IVDD expiry date according to Regulation (EU) 2022/112.
Current	3674433	Amendment – extension to device shelf life claim from 12 months to 18 months.

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