

EC Design-Examination Certificate

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

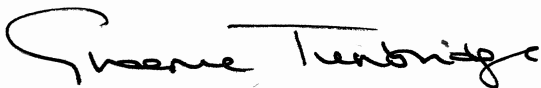
No. **CE 742686**
Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

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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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 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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