

EC Design-Examination Certificate

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

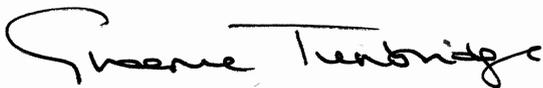
No. **CE 708527**
Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

In respect of:

Xpert HCV 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: **2022-03-25**

Expiry Date: **2025-03-08**

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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.

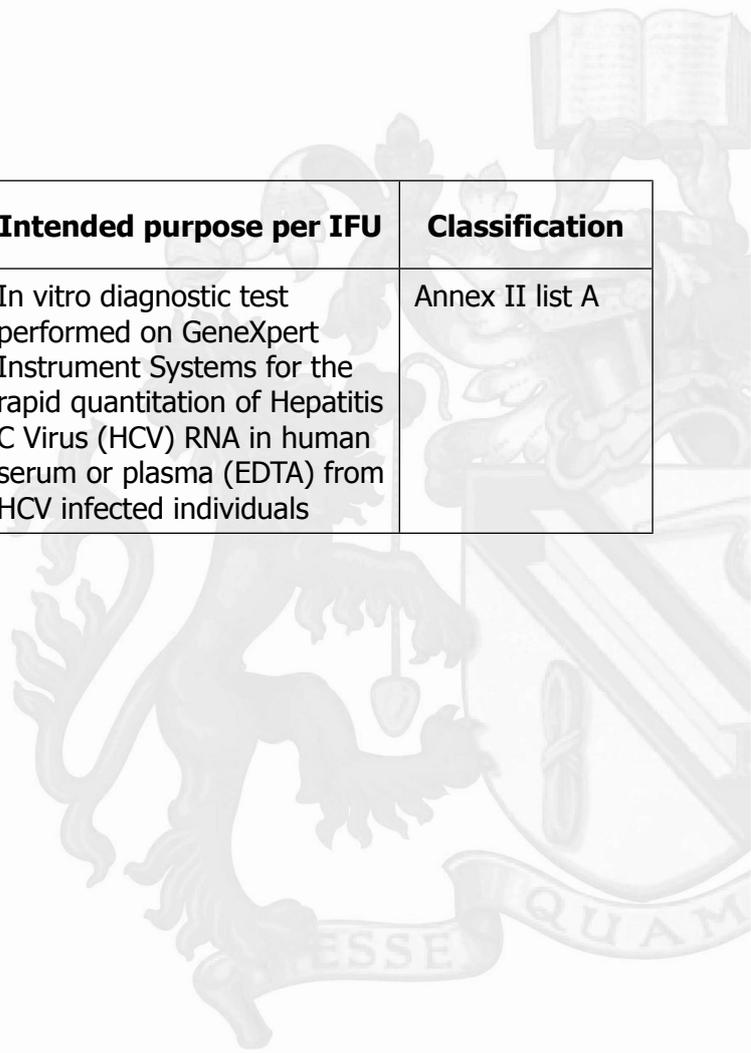
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Supplementary Information to CE 708527

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| Catalogue Number | Device Name | Model, Type | Intended purpose per IFU | Classification |
|-----------------------------------|----------------------|-------------|--|-----------------|
| GXHCV-VL-CE-10; GXHCV-VL-IN-10 | Xpert HCV Viral Load | N/A | In vitro diagnostic test performed on GeneXpert Instrument Systems for the rapid quantitation of Hepatitis C Virus (HCV) RNA in human serum or plasma (EDTA) from HCV infected individuals | Annex II list A |



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Certificate History

| Date | Reference Number | Action |
|------------------|------------------|--|
| 28 March 2019 | 9738795 | First issue. Transfer from another Notified Body. |
| 09 August 2019 | 3057082 | Change: extension of shelf life to 18 months. |
| 09 March 2020 | 3145535 | Renewal. |
| 25 February 2021 | 3289905 | Change: intended use update; addition of seroconversion panels in the performance claim; diagnostic specificity data update. |
| 14 May 2021 | 3411679 | Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2. |
| Current | 3643376 | Change of IVDD expiry date according to Regulation (EU) 2022/112. |

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