

EC Design-Examination Certificate

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

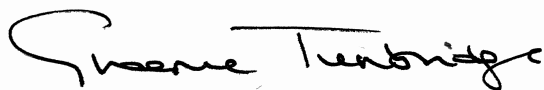
No.**CE 708527****Issued To:****Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden**

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.

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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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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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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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