EC Design-Examination Certificate

TÜVRheinland®

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

Registration No.: IL 1782924-1

Manufacturer: QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Germany

Products: Hepatitis Diagnostics

Replaces Certificate, Registration No.: IL 60110630 0001

Products included:

artus HBV QS-RGQ Kit
artus HBV RG PCR Kit

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Report No.: 3348476-170

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.