TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4

In Vitro Diagnostic Medical Devices

Registration No.: IL 60110630 0001

Report No.: 21248738 001

Manufacturer:

QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Product Identification:

Hepatitis Diagnostics

(see attachment for products included)

Replaces Certificate, Registration No.: IL 60082478 0001

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.

Expiry Date: 2021-05-16

Effective Date: 2016-05-17

Date: 2016-05-06

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60110630 0001
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Manufacturer:
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Products included:

artus HBV QS-RGQ Kit
artus HBV RG PCR Kit
artus HBV TM PCR Kit

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2016-05-06

Dr. H. Lüdemann