

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60130501 0001

Report No.: 21197420 004

Manufacturer: QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Product

Identification: Hepatitis Diagnostics

Products: artus HCV RT-PCR Kits
Product details: see attachment
Replaces Certificate, Registration No.: IL 60086817 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: 2023-06-27

Notified Body

Effective Date: 2018-06-28

Date: 2013-06-22


Dipl.-Ing. Sven Hoffmann



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.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: IL 60130501 0001
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Products included:

- artus HCV QS-RGQ Kit
- artus HCV RG RT-PCR Kit

Date: 2018-06-22

Notified Body




Dipl.-Ing. Sven Hoffmann