TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4

In Vitro Diagnostic Medical Devices

Registration No.: IL 60130481 0001

Report No.: 21197421 005

Manufacturer:

QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Product Identification:

HIV Diagnostics

Products: artus HI Virus-1 RT-PCR Kits
Product details: see attachment
Replaces Certificate, Registration No.: IL 60086818 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

Effective Date: 2018-06-28

Date: 2018-06-22

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60130481 0001
Report No.: 21197421 005

Manufacturer: QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
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Products included:

- artus HI Virus-1 QS-RGQ Kit
- artus HI Virus-1 RG RT-PCR Kit

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-06-22

Dipl.-Ing. Sven Hoffmann