

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6

Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60110379 0001

Report No.: 21248184 001

Manufacturer: QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Deutschland

Products: Molecular biological in vitro diagnostic medical devices
for detection of nucleic acids

(see attachment for products included)

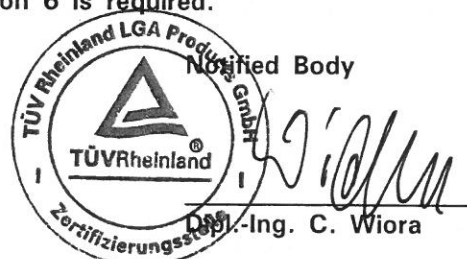
Replaces EC Certificate, Registration No.: HL 60090892 0001

Expiry Date: 2021-05-08

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2016-05-09

Date: 2016-05-09



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.: HL 60110379 0001
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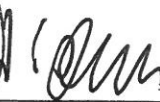
Products included:

- PCR reagents for the detection of Chlamydia trachomatis
- PCR reagents for the detection of Cytomegaloviruses
- PCR reagents for the detection of Hepatitis B viruses
- PCR reagents for the detection of Hepatitis C viruses
- PCR reagents for the detection of HI-viruses

Date: 2016-05-09



Notified Body


Dipl.-Ing. C. Wiora