EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1782924-1

Manufacturer:
QIAGEN GmbH
Qiagen Str. 1
40724 Hilden
Germany

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

Replaces EC Certificate, Registration No.: HL 60110379 0001

Products included:

- PCR reagents for the detection of Chlamydia trachomatis and Chlamydophila pneumoniae
- 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

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.

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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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.