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 60131049 0001

Report No.: 21249753 006

Manufacturer:

QIAGEN Sciences LLC
19300 Germantown Road
Germantown MD 20874
USA

Products:

Assays on "hybrid capture" technique for the detection of Chlamydia trachomatis:

- Hybrid Capture 2 CT-ID DNA Test (Catalogue # 5135-1330)

Replaces Certificate, Registration No.: HL 60098838 0001

Expiry Date: 2023-07-21

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: 2018-07-22

Date: 2018-07-22

Notified Body

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.