EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60131050 0001

Report No.: 21249753 007

Manufacturer:

QIAGEN Sciences LLC
19300 Germantown Road
Germantown MD 20874
USA

Products:

The scope covers only aspects of manufacture concerned with securing and maintaining sterile conditions:

- Hybrid Capture Female Swab Specimen Collection Kit (Catalogue # 5123-1220), sterile

Replaces Certificate, Registration No.: DD 60098839 0001

Expiry Date: 2023-07-21

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III 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 93/42/EEC concerning medical devices with the identification number 0197.