

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 60125765 0001

Report No.: 16801521 007

Manufacturer: W.H.P.M.
BioResearch & Technology Co., Ltd.
No.2 Zhongxin Street
LouZiZhuang, Jinzhanxiang
Chaoyang District
Beijing 100018
China

Products: in vitro medical devices for self-testing
Please attachment for products included:
Rep: user Approval, Registration No.: HL 60079657 0001

Expiry Date: 2020-01-17

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: 2018-01-18

Date: 2018-01-16



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**

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Product groups:

- Pregnancy Tests
- Ovulation Tests
- Follicle Stimulating Hormone Tests
- Coagulation Tests
- Coagulation Tests (Thrombin Time)
- Coagulation Tests (Fibrinogen and D-Dimer Tests)
- Coagulation Tests (Hemoglobin and Transferrin Tests)
- Drugs or Abuse Tests

Date: 2018-01-16

