

## 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:  
Reg. used Approval, Registration No.: HL 60079957 0001

Expiry Date: 2023-01-17

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: 2023-01-16



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

