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

New attachment for products included:

Rapid Acon Approval, Registration No.: EL 60070957 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

Notified Body

X. Ren

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.

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60125765 0001
Report No.: 16801521 007

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

Product groups:

- Pregnancy Tests
- Ovulation Tests
- Follicle Stimulating Hormone Tests
  Occult Blood Tests
- Occult Blood Tests (Transferrin Tests)
  Occult Blood Tests (Hemoglobin and Transferrin Tests)
- Drugs of Abuse Tests

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

X. Ren

Date: 2018-01-16