

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2101523-1

Organization: W.H.P.M Bioresearch & Technology Co., Ltd.  
No.2 Zhongxin Street, Louzizhuang, Jinzhanxiang, Chaoyang District,  
100018 Beijing, P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro  
Diagnostic Test Kits used in the Detection of Fertility Testing, Pregnancy  
Testing, Drugs of Abuse, Cancer and Infection Diseases including Home  
Use, near Patient in-vitro Diagnostic Devices, Automatic Fecal  
Immunochemical Test Analyzers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190129641 110

Effective date: 2021-01-18

Expiry date: 2024-01-17

Issue date: 2021-01-13

  
Jing Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

1 / 1



TÜV Rheinland LGA Products GmbH • 51105 Köln

W.H.P.M Bioresearch & Technology Co., Ltd.  
No.2 Zhongxin Street, Louzizhuang, Jinzhanxiang, Chaoyang District,  
100018 Beijing, P.R. China

Contact

Tel. +49 911 655-5225  
Mail: [service@de.tuv.com](mailto:service@de.tuv.com)

Date January 13, 2021

**Application for: QMS**

Certificate No. : SX 2101523-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2101523-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Jing Zhang  
Certification body

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

Phone. +49 911 655 5225  
Fax +49 911 655 5226  
[service@de.tuv.com](mailto:service@de.tuv.com)  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller