

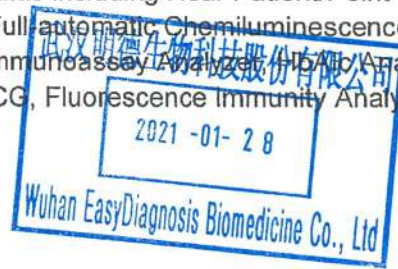
# Certificate

Quality Management System  
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.  
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley  
International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin  
2nd RD, East Lake Hi-Tech Development Zone  
Wuhan, 430074 Hubei P.R. China

Scope: Design and Development, Manufacture and Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbA1c Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.



武汉明德  
Wuhan Eas

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.: 190129510 110  
Effective date: 2021-01-27  
Expiry date: 2024-01-26  
Issue date: 2021-01-25



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

# Certificate

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

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.  
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics  
Valley International Biopharmaceutical Enterprise Accelerator, No.388,  
Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan,  
430074 Hubei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care
/02	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. Room 4, 1st Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd Road, East Lake High-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of Immune Quantitative Analyzer, Full-automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbA1c Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.

Report No.: 190129510 110

Effective date: 2021-01-27

Expiry date: 2024-01-26

Issue date: 2021-01-25



  
Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany  
2 / 3

物科  
2021-01  
agnosis B

# Certificate

Quality Management System  
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.  
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics  
Valley International Biopharmaceutical Enterprise Accelerator, No.388,  
Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan,  
430074 Hubei, P.R. China

The scope of certification also covers the following:

/03	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. No.A8, 2-2 Building, Optics Valley Biomedical Industry Park Phase II, No.858 Gaoxin Road, Wuhan East Lake Hi-tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status as well as for the Monitoring of the Disease Status including Near Patient/Point of Care. Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full-automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbA1c Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.
-----	---	--

Report No.: 190129510 110

Effective date: 2021-01-27

Expiry date: 2024-01-26

Issue date: 2021-01-25



Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany  
3 / 3

股份  
28  
edicin

TÜV Rheinland LGA Products GmbH • 51105 Köln

Wuhan EasyDiagnosis Biomedicine Co., Ltd.  
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics  
Valley International Biopharmaceutical Enterprise Accelerator, No.388,  
Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan,  
430074 Hubei, P.R. China

Contact

Tel. +49 911 655-5225  
Mail: service  
@de.tuv.com

Date January 25, 2021

**Application for: QMS**

Certificate No. : SX 2055510-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2055510-1 replacing the previous certificate.

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

Best regards,

Wenxiang Zhang  
Certification body



有限公司  
Co., Ltd

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  
[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 Scheiler