

SARS-CoV-2 Antigen Test kit

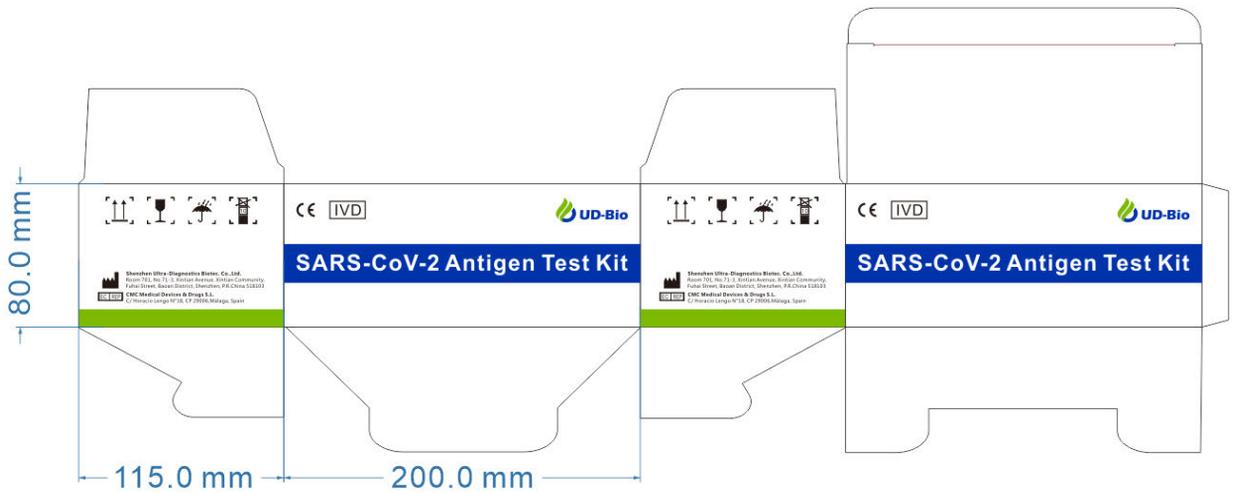
(Colloidal Gold Chromatographic Immunoassay)



Component	Quantity	Contain	Weight	Dimension (mm)
Test card	25 packs	Test card ×25 pcs Desiccant×25 pcs	300g	200×115×80
Extraction tube	1 pack	Extraction tube×25 pcs		
Nozzle cap	2 packs	Nozzle cap× 25 pcs		
Swab	25 packs	Nasopharyngeal swab×25 pcs		
Extraction buffer	1 bottle	Extraction buffer×8mL		
Instruction for use	1 copy	1 copy		

Product Label Template

Packing drawing of the kit:



CE Certificate in Spanish MOH No. RPS/2401/2020

La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/2401/2020
Fecha Registro:	19/10/2020 09:14:00
Nº registro General:	RPS/2401/2020
Oficina:	ETEL
Nº registro Oficina:	RPS/2401/2020

Registro de Responsables de Productos Sanitarios - RPS/2401/2020

Datos de la notificación

Datos de registro

Nº Registro: Fecha Registro:

Datos del Responsable

Tipo de Responsable (*): Tipo de entidad:

CIF (*): Nombre (*):

Dirección (*):

Localidad (*):

Provincia (*): CP (*):

Teléfono (*): Fax:

e-mail (*): Web:

Datos del Fabricante

Nombre o Razón Social (*):

Dirección (*):

Localidad (*):

País (*): CP:

Teléfono (*): Fax:

e-mail (*): Web:

Datos de Productos Comunicados

Estatus (*):

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) ANTIGEN TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY)	Diagnostico In Vitro	Primera Comunicación	

Declaration of Conformity



No. UD/025/202010

Declaration of Conformity

Manufacturer	Shenzhen Ultra-Diagnostics Biotec. Co.,Ltd. Room 701, No.71-3, Xintian Avenue, Xintian Community, Fuhai Street, Baoan District, Shenzhen, P.R.China 518103
European Representative	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo N°18, CP 29006,Málaga, Spain
Product name	Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
Models	25T/Kit
Classification	Others
Conformity Assessment Route	Annex III of Directive 98/79/EC

Shenzhen Ultra-Diagnostics Biotec. Co.,Ltd.

Herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards.All supporting documentations are retained under the premises of the manufacturer

Standards Applied	EN ISO 13485:2016	EN ISO 17511:2003
	EN ISO 14971:2012	EN ISO 23640:2015
	EN ISO 18113-1:2011	EN ISO 15223-1:2016
	EN ISO 18113-2:2011	EN 13612:2002



Place, Date

SHENZHEN, October 09, 2020

Position

Management Representative

Signature



Shenzhen Ultra-Diagnostics Biotec. Co., Ltd

was founded in 2016 in Shenzhen, China. Our brand is UD-Bio. It is a national high-tech company specialized in developing, researching, manufacturing and selling IVD products including instruments and reagents. Our products cover thromboelastography hemostasis system, coagulation system, specific protein system, immunofluorescence system and biochemistry reagents.

We have professional R&D, manufacture, sales and service team, there are 100 employees in total and 40% of our staff are engaged in R&D.

The total area of our manufacturing plant and laboratories are more than 5000 sqm. Our state-of-the-art manufacture facility is ISO13485:2016 and GMP requirement compliant. Most of our products are CE approved and have certificates for Exportation of medical products.



Medical Device Manufacturing License

医疗器械生产许可证

许可证编号: 粤食药监械生产许 20183151 号

企业名称: 深圳优迪生物技术有限公司

生产地址: 深圳市宝安区福海街道新田社区新田大道71-3号
701, 深圳市宝安区福永街道凤凰第一工业区华源
小区B幢第四层C

法定代表人: 李秋霞

生产范围: 见医疗器械生产产品登记表

企业负责人: 艾峰

住 所: 深圳市宝安区福海街道新田社区新田大道71-3
号701

发证部门: 广东省药品监督管理局



有效期限: 至 2023 年 05 月 20 日 发证日期: 2019 年 02 月 14 日

国家食品药品监督管理总局制

Peoples' Republic of China

Medical Device Manufacturing License

License No. Guangdong Food and Drug Administration 20183151



Company Name:
Shenzhen Ultra-Diagnostics Biotech Co.,Ltd

Manufacturing Address:
Room 701, No.71-3, Xintian Avenue, Xintian
Community, Fuhai Street, Baoan District
Shenzhen, P.R.China

Registered Address:
Room 701, No.71-3, Xintian Avenue, Xintian
Community, Fuhai Street, Baoan District
Shenzhen, P.R.China

Area C, 4th Floor, Building B, Huayuan
Community, Fenghuang 1st Industrial Park,
Fuyong Street, Baoan District, Shenzhen,
P.R.China

Scope of Manufacture:
Manufacture of clinical examination and
analytical apparatus and diagnostic reagent

Legal Representative: Li Qiuxia

Registration Department:
Guangdong Food and Drug Administration

Responsible Person: Ai Feng

Valid Date: May 20th, 2023

Date of Issue: Feb 14th, 2019

Business License



营业执照

统一社会信用代码 91440300MA5DFC619U

名称 深圳优迪生物技术有限公司
主体类型 有限责任公司
住所 深圳市宝安区福海街道新田社区新田大道
71-3号701
法定代表人 李秋霞
成立日期 2016年06月27日



重要提示

- 1、商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
- 2、商事主体经营范围和许可审批项目等有关事项及年报信息和其他信用信息，请登录深圳市市场和质量监督管理委员会商事主体信用信息公示平台（网址<http://www.szcredit.com.cn>）或扫描执照的二维码查询。
- 3、商事主体须于每年1月1日-6月30日向商事登记机关提交上一年度的年度报告。商事主体应当按照《企业信息公示暂行条例》等规定向社会公示商事主体信息。



登记机关

2017年04月06日



EN ISO 13485: 2016



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Shenzhen Ultra-Diagnostics Biotech.
Co., Ltd.**
**Room 701, No.71-3, Xintian Avenue
Xintian Community, Fuhai Street, Baoan District
518103 Shenzhen
P.R. China**

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-06
Certificate Registration No.: SX 60138097 0001
An audit was performed. Report No.: 17054659 002
This Certificate is valid until: 2022-06-14

Certification Body



Date 2020-01-06



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

EN ISO 13485: 2016



Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138097 0001
Report No.: 17054659 002

Organization:

**Shenzhen Ultra-Diagnostics Biotec.
Co., Ltd.**
Room 701, No.71-3, Xintian Avenue
Xintian Community, Fuhai Street, Baoan District
518103 Shenzhen
P.R. China

Scope:

Design and Development, Manufacture and Distribution of in-vitro diagnostic analyzers and reagents used in the diagnosis, detection of coagulation, immune status and disease status including point of care in-vitro diagnostic medical devices

Certification Body



Date: 2020-01-06



EN ISO 13485: 2016



Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138097 0001
Report No.: 17054659 002

Organization: Shenzhen Ultra-Diagnostics Biotec.
Co., Ltd.
Room 701, No.71-3, Xintian Avenue
Xintian Community, Fuhai Street, Baoan District
518103 Shenzhen
P.R. China

Scope: Site included:

Area C, 4th Floor, Bulding B, Huayuan Community,
Fenghuang 1st Industrial Park, Fuyong Street,
Baoan District, Shenzhen, P.R.China

Manufacture of reagent of in-vitro diagnostic
reagents used in the diagnosis, detection of coagulation,
immune status and disease status including point of care
in-vitro diagnostic medical devices

Certification Body



Date: 2020-01-06



EN ISO 13485: 2016

**Business Stream Products
Certification Department**



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shenzhen Ultra-Diagnostics Biotec.
Co., Ltd.
Xintian Community, Fuhai Street, Ba
518103 SHENZHEN
CHINA

Contact

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

Date January 06, 2020

Application for : QMS
Certificate No. : SX 60138097 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60138097 0001.

Kind regards

Certification body

Wenxiang Zhang



Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
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Web www.tuv.com/safety

Board of Management

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Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490