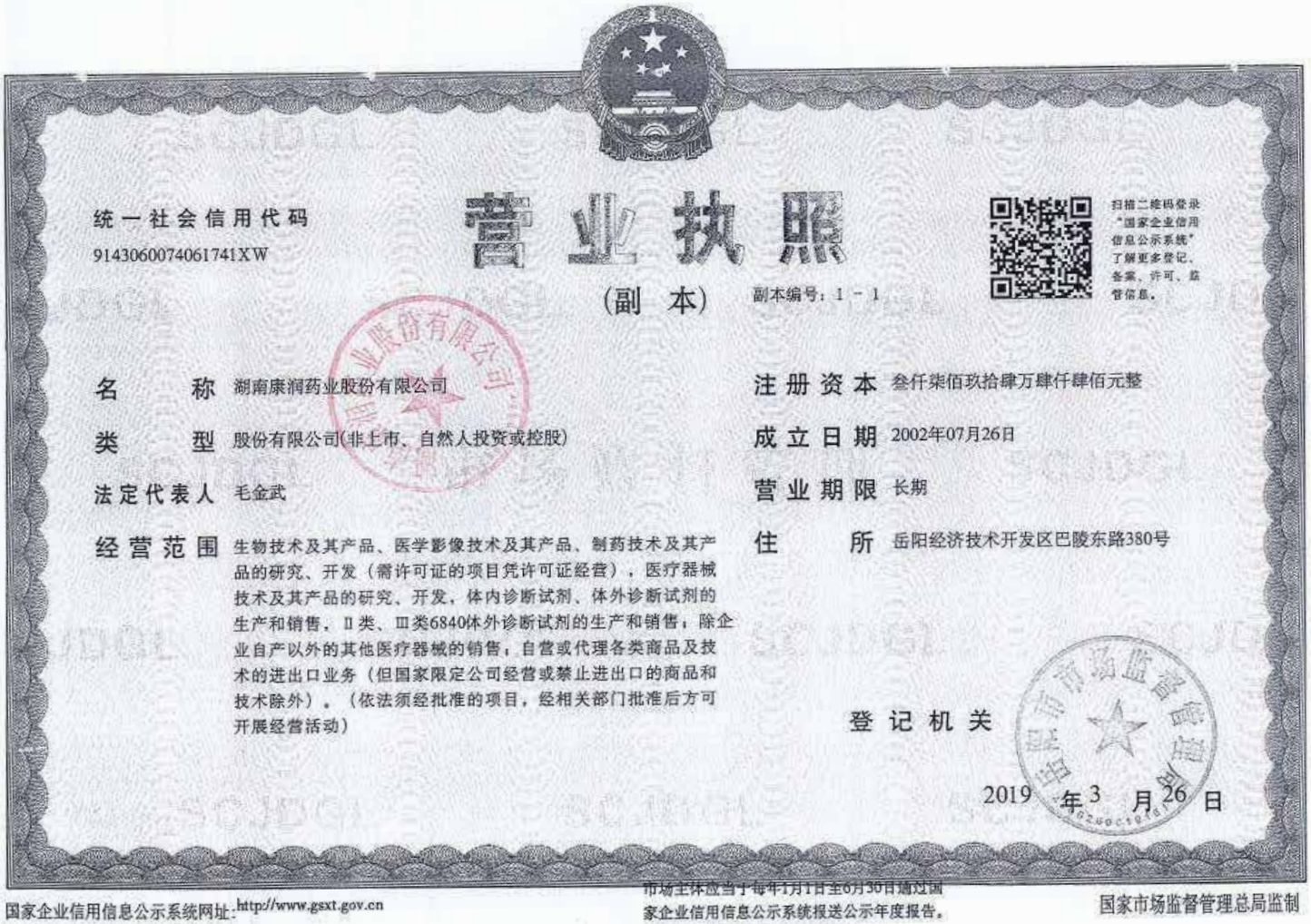
CERTIFICADOS
PRUEBAS COVID



统一社会信用代码

91430600740617 41XW

营业执照

（副 本）

副本编号：1 - 1

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　湖南康润药业股份有限公司

类　　型　股份有限公司(非上市、自然人投资或控股)

法定代表人　毛金武

经营范围　生物技术及其产品、医学影像技术及其产品、制药技术及其产品的研究、开发（需许可证的项目凭许可证经营），医疗器械技术及其产品的研究、开发，体内诊断试剂、体外诊断试剂的生产和销售，Ⅱ类、Ⅲ类6840体外诊断试剂的生产和销售；除企业自产以外的其他医疗器械的销售；自营或代理各类商品及技术的进出口业务（但国家限定公司经营或禁止进出口的商品和技术除外）。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　叁仟柒佰玖拾肆万肆仟肆佰元整

成立日期　2002年07月26日

营业期限　长期

住　　所　岳阳经济技术开发区巴陵东路380号

登记机关

2019 年 3 月 26 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

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医疗器械生产许可证

许可证编号：湘食药监械生产许20170011号

企业名称：湖南康润药业股份有限公司　　生产地址：湖南省岳阳市经济技术开发区巴陵东路

法定代表人：毛金武　　生产范围：III类：III类:6840- 体外诊断试剂

企业负责人：孙伯钊

住　　所：岳阳经济技术开发区巴陵东路380号　　发证部门：湖南省药品监督管理局

有效期限：至 2022 年 04 月 12 日　　发证日期：2019 年 08 月 21 日

国家药品监督管理局制

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Record number: KR10.2.5-GCOV-S002-E001-00	effective date: February 10, 2020
Corresponding document No: KR10.2.5-GCOV-S002	Valid until: June 30, 2024
Record name: **SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold) product certificate of analysis**	

Report No: C-0232020005

Name of specimen	SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)	Material code	C-1-023
Verification basis	《Quality standard of SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)》	Batch number	20200302
Production department	Third workshop	Specification	40 tests/kit
Production output	5000 kits	Expiration date	September 20, 2021
Quantity of inspection	4 kits	Sampling person	Yu Gaowei
Sampling date	March 21, 2020	Reporting date	March 21, 2020

	Verification project	Verification standard	Verification result
Verification result	Appearance	Shall comply with the regulations	Pass
	Width of film strip	≥2.5mm	Pass
	Liquid moving speed	Should not lower than 10mm/min	Pass
	Compliance rate of positive references	The test result should be 8/8 with 8 enterprise positive references.	Pass
	Compliance rate of negative reference	The test result should be 10/10 with 10 enterprise negative references.	Pass
	Minimum detection limit	L1-L2 should be positive, L3 can be negative or positive, L4 should be negative.	Pass
	Repeatability	J1 should be negative, J2 should be IgM and IgG positive.	Pass
Conclusion	This batch of samples was certified according to 《Quality standard of SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)》, the results comply the regulations.		
Remarks	/		

QC Supervisor: Yi Cun

Quality manager: Wu Gangqiang

Validation Report

Product Name: SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)

Validation indicators: Specificity,Sensitivity,Cross Reactivity, Interferences

Hunan Runkun Pharmaceutical Co.,Ltd.

1.Objective: To verify the analytical performance of SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)

2. Validation indicators: Specificity, Sensitivity, Cross Reactivity, Interferences.

3. Verification procedure:

Place the reagents and specimens to room temperature before testing.Open the pouch, take out the test card. Take10μL of specimensanddrop on the specimen hole of the test card, then add 2 drops (80 μL) of specimen diluentinto the specimen hole.Wait for 10 minutes, and read the results by viewingthe detection window. All the test should be finished in 1 hour.

3.1 Specificity and Sensitivity:

206 specimens which include 59 confirmed case specimens and 147 negative specimens were tested by SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold),the result of specificity and sensitivity are show below.

Reagents	Specimens		Total
	Positive specimens	Negative specimens	
Positive	55	2	57
Negative	4	145	149
Total	59	147	206

Results analysis:

Sensitivity: 93.22%(95% CI:82.73%~97.81%).

Specificity:98.64%(95% CI: 94.67%~99.76%).

3.2 Cross Reactivity

Specimens which tested positive with parainfluenza virus antibody,influenza A antibody,influenza B antibody,hepatitis B surface antigen,hepatitis C virus antibody,treponema pallidum antibody,HIV antibody,EB virus antibody from patients were investigated with by SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold), the results showed no cross reactivity.

Specimens	Total number	Result	
		Positive	Negative
influenza A antibody	5	0	5
influenza B antibody	2	0	2
parainfluenza virus antibody	2	0	2
hepatitis B surface antigen	5	0	5
hepatitis C virus antibody	3	0	3
treponema pallidum antibody	3	0	3
HIV antibody	2	0	2
EB virus antibody	2	0	2
Total	24	0	24

3.3 Interferences

The specimens with hemoglobin, triglyceride and bilirubin will interfere the test results, and the maximum allowable concentrations are show below.

Substance	Concentration	Result
Hemoglobin	5mg/ml	Negative
Triglyceride	10mg/ml	Negative
Bilirubin	0.2mg/ml	Negative

Material safety data sheet (MSDS)

Item 1: Chemical name and manufacturer information

Product name:SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

Manufacturer/supplier: Hunan RunKun Pharmaceutical Co., Ltd.

Production address: NO.380 Baling East Road, Economic-Technological Development Zone, Yueyang, Hunan, 414000, P.R.China.

Contact:0730-8725966

Emergency call:0730-8725967

Item 2: Chemical composition information

Chemical properties: mixtures

Description: Plastic card, 0.9% sodium chloride solution

Dangerous ingredient: none

Item 3: hazard information

Classification of substances or mixtures:

Classified according to Regulation (EC)1272/2008

Products not classified according to CLP regulations.

Classification is invalid according to Directive 67/548/EEC or Directive 1999/45/EC

Information on the particular harm to human being and the environment:

No product marking is required based on the calculation procedure of the latest effective version of the "EU General Classification Guidelines for Preparations".

According to the calculation method of the "EC General Classification Guidelines for preparation" published in the previous version, the product may not be classified.

The product is not subject to the EC Directive and the Identification Requirements Regulations of the 《Hazardous Substances Regulation》 (GefStoffV).

Other hazards

PBT: Not applicable.

vPvB: Not applicable.

Item 4:First aid measures

First aid measures

General information immediately take off the clothes that are soiled by the product.

Once inhaled, take the affected person outside and comfortably into position, just in case.

Wash and rinse thoroughly with water and soap immediately after skin contact. Consult a doctor if skin irritation persists.

After eye contact, rinse your eyes under running water for a few minutes. Then consult a doctor.

Rinse your mouth with water immediately after swallowing and seek medical advice immediately.

Doctor instructions

There are no special measures to treat symptoms;

The most important acute and delayed symptoms and effects.

No further information.

Instructions for immediate medical treatment and special treatment.

No other relevant information is available

Item 5: Fire control measures

Fire extinguishing agent

Suitable extinguishing agent

Carbon dioxide, fire extinguishing agent spraying. Extinguishing a fire with spray water or anti-alcohol foam.

For safety reasons, inappropriate fire extinguishing agents are fully sprayed with water.

Special hazards caused by substances or mixtures.

The formation of toxic gases in heating or combustion.

Firefighter Notes

Protective equipment: Wearing a self-contained respirator.

Additional information

Disposal of fire debris and contaminated fire water in accordance with official regulations.

Item 6: Emergency handling of leakage

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Stay away from unprotected people. Ensure adequate ventilation to avoid dust.

Use a respiratory protection device to prevent the effects of smoke, dust/aerosols. Avoid contact with eyes and skin.

Environmental considerations:

Products are prohibited from entering sewage systems or water bodies. No access to the ground/soil.

Methods and materials for containment and cleaning:

Mechanical collection.

The collected materials are handled in accordance with the regulations. Avoid dust.

Ensure adequate ventilation.

Refer to other sections

Clean the accident area carefully.

For information on disposal, see section 13.

For information on personal protective equipment, see section 8.

Item 7: Operation and storage

Operation

Precautions for safe operation

Ensure that the workplace is well ventilated and prevents dust formation.

Avoid contact with eyes and skin and spill.

Prepare to use eye-wash vessels (bottles) in the workplace.

Information on explosion prevention and fire prevention: no special measures required.

Safe storage conditions, including any incompatibilities

Storage

Storage rooms and containers to meet the requirements:

Stored only in the original container, floor slots without sockets are available.

Information about storage on a common storage device:

Keep away from food.

Keep away from oxidants.

More information about storage conditions:

Keep the container sealed and stored in a cool place.

Recommended storage temperature:4-30℃

Specific end-use: No more information.

Item 8: Contact control and personal protection measures

Additional information about technical system design: No more data

Control parameters

Extreme components that need to be monitored in the workplace: This product does not contain any significant amount of material, which must be monitored in the workplace.

Additional information: Based on lists that are valid during compilation .

Exposure control

Personal protection equipment

General protective hygiene

Stay away from food and drinks. Wash your hands at the end of rest and work. Avoid contact with eyes and skin.

Do not inhale dust/smoke/mist.

Take off all contaminated clothes immediately.

Hand protections:

Protective gloves.

Use only Class III chemical protective gloves with CE marking.

Glove material must be impermeable and resistant to products/substances/preparations.

Due to lack of testing, it is not possible to provide recommended glove materials for the product/preparation/chemical mixture.

Select glove materials for penetration time, diffusion rate and degradation.

Glove material

The choice of suitable gloves depends not only on the material, but also on the further marking of the quality and varies from manufacturer to manufacturer. Since the product is a formulation of a variety of substances, the resistance of the glove material cannot be calculated in advance and must be checked before use.

Penetration time of glove material

The exact time must be determined by the manufacturer of the protective gloves and must be observed.

Gloves made of the following materials do not fit:

Leather Gloves, Power Gloves.

Protect your eyes.

Physical protection: protective clothing.

Item 9: Physical and chemical properties

Appearance: solid

Color: white

Odor: no odor

Melting point/melting range: not determined

Boiling point/range: not determined

Flash point: not applicable

Spontaneous combustion: the product will not spontaneous combustion

Explosion hazard: product does not explode

Density is pending

Water solubility/water miscibility: not applicable

Item 10:Stability and reactivity

Heat decomposition/avoidance conditions: if used to specifications, it is not decomposed.

If used as directed, there is no dangerous reaction.

Conditions to avoid: No more information available.

Incompatible materials: strong oxidants

Dangerous decomposition products: none, if stored and handled correctly.

Item 11: Toxicological information

Toxicological data

Acute toxicity:

Primary stimulus:

On the skin: May be irritating

To the eye: May be irritating

Allergy: Prolonged or repeated exposure may cause allergic reactions to sensitive people

Other toxicological information:

According to the latest calculation method of the "General EC Preparation Classification Guidelines", the product may not be classified.

Item 12: Ecological information

Toxicity

Aquatic toxicity: no more information.

No more information on persistence and degradation.

Environmental system behavior:

There is no further information about potential bioaccumulation.

No further information on fluidity in the soil.

Ecotoxicity: Undetermined

Other ecological information:

Water Hazard Level 3 (German Regulation) (Self-Assessment): Extremely Dangerous to Water.

Even small amounts do not allow products to enter groundwater, water bodies or sewage systems. Even if very small amounts of water leak into the soil, it can cause harm to drinking water.

Evaluate results in PBT and vPvB:

PBT: Not applicable.

vPvB: Not applicable.

Other adverse reactions: No more information.

Item 13:Waste disposal

Waste disposal method

When recommending disposal, local regulations issued by the authorities must be observed.

European waste separation

180000 Waste from human or animal health and/or related studies

180200 Research, diagnose, treat or prevent waste from animal-related diseases

180205 Chemical substances consisting of or containing hazardous substances

Uncleaned packaging:

Recommendation: Disposals must be carried out in accordance with official regulations.

Item 14:Transportation information.

UN number

ADR, IMDG, IATA invalid

Official United Nations Transport Name

ADR, IMDG, IATA invalid

Transport risk level

ADR, IMDG, IATA invalid

Packaging group

ADR, IMDG, IATA invalid

User Special Notes: N/A

Bulk shipping in accordance with MARPOL73/78 Annex II and IBC Rules: N/A.

Transport/Other information: no hazards according to the above specifications.

Item 15:Regulatory information

Safety, health and environmental regulations/laws for substances or mixtures

National regulation

Water Hazard Rating: Water Hazard Level 3 (Self-Assessment): Extremely Dangerous to Water.

Chemical safety assessment: chemical safety assessment has not yet been carried out.

Item 16: Other information

These data are based on our existing knowledge; however, they do not constitute any guarantee of specific product functions and do not establish legally binding contractual relationships.

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海 运
By Sea

NO.2020158800

CNAS 中国认可 检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）

Sample Name: SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

委托单位： 湖南康润药业股份有限公司

生产单位： 湖南康润药业股份有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

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By Sea

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3. 鉴定书无主检、审核、批准签字无效。
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   The client must guarantee that samples and documents provided for appraisal are consistent with the goods to be transported. Otherwise, the client shall bear all legal responsibilities and other consequences due to it.
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    The authenticity of the certification can be verified by our website(www.ghs.cn)or the QR code in the certification.
11. 送检申请可登入本公司网站 www.ghs.cn 进行网上委托。
    The application of the certification can be done via our website: www.ghs.cn.

地址：上海市光复西路2779号接待大厅
Address: Reception Hall, Shanghai Research Institute of Chemical Industry Co., Ltd, No.2779 West Guangfu Road, Shanghai, China.
邮编(Post code): 200062
电话(Tel):(008621)31765555
邮箱(Email): center@ghs.cn
网址(Website): www.ghs.cn

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020158800

样品名称 Sample Name	中文 Chinese	新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）
	英文 English	SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
委托单位 Consignor		湖南康润药业股份有限公司
生产单位 Manufacturer		湖南康润药业股份有限公司
检验方法、程序 Inspection Methods and Procedures		国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)
样品外观与气味 Appearance & Odor		白色纸盒（内含无色透明液体和白色塑料试剂板），稍有气味 White Paper box(containing colorless transparent liquid and white plastic reagent board),Weak odor
IDENTIFICATION CONCLUSION 鉴定结论		1. 危险性识别(Hazards identification) 无。 None. 2. 海运按照IMO IMDG Code办理的类项(Suggestion according to IMO IMDG Code) 可按非限制性货物条件办理。 The substance is not subject to IMO IMDG Code. 3. 包装要求(Packaging requirements) 无。 None. 检验日期: Inspection Date: 2020-03-31 签发日期: Issue Date: 2020-04-01 生效日期: Effective Date: 2020-04-01
备注 Comment		无。 None.

批准 Approver: 张小秋 审核 Checker: 黄学雄 主检 Appraiser: 宋翠丹

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020158800

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:759118-

报告结束

PROTC LIFE®

公 路
By Road

NO.2020158803

CNAS 中国认可 检验 INSPECTION CNAS 标0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

普通货物

样品名称： 新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）

Sample Name: SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

委托单位： 湖南康润药业股份有限公司

生产单位： 湖南康润药业股份有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司
Shanghai Research Institute of Chemical Industry Testing Co., Ltd

公 路
By Road

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   The certification is invalid if it is forged or altered.
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   The client must guarantee that samples and documents provided for appraisal are consistent with the goods to be transported. Otherwise, the client shall bear all legal responsibilities and other consequences due to it.
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    The application of the certification can be done via our website: www.ghs.cn.

地址：上海市光复西路2779号接待大厅
Address: Reception Hall, Shanghai Research Institute of Chemical Industry Co., Ltd, No.2779 West Guangfu Road, Shanghai, China.
邮编(Post code): 200062
电话(Tel):(008621)31765555
邮箱(Email): center@ghs.cn
网址(Website): www.ghs.cn

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货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2020158803

样品名称 Sample Name	中文 Chinese	新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）
	英文 English	SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
委托单位 Consignor		湖南康润药业股份有限公司
生产单位 Manufacturer		湖南康润药业股份有限公司
检验方法、程序 Inspection Methods and Procedures		JT/T 617-2018《危险货物道路运输规则》第2、3部分 JT/T 617-2018 Regulations concerning road transportation of dangerous goods Part 2 and 3
样品外观与气味 Appearance & Odor		白色纸盒（内含无色透明液体和白色塑料试剂板），稍有气味 White Paper box(containing colorless transparent liquid and white plastic reagent board), Weak odor
IDENTIFICATION CONCLUSION 鉴定结论		1. 危险性识别(Hazards identification) 无。 None. 2. 公路运输按照JT/T 617-2018办理的类项(Suggestion according to JT/T 617-2018) 可不受规则限制。 The substance is not subject to JT/T617-2018. 3. 包装要求(Packaging requirements) 无。 None. 检验日期: Inspection Date: 2020-03-31 签发日期: Issue Date: 2020-01-01 生效日期: Effective Date: 2020-04-01
备注 Comment		无。 None.

批准 Approver: 张小波 审核 Checker: 董学胜 主检 Appraiser: 胡翠丹

PROTC LIFE®

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020158803

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:138735-

报告结束

空 运
By Air

NO.2020158798

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）

Sample Name: SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

委托单位： 湖南康润药业股份有限公司

生产单位： 湖南康润药业股份有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

PROTC LIFE®

声　明
Statement

1. 鉴定书无上海化工院检测有限公司检验检测专用章、二维码无效。
   The certification is invalid if it is not affixed the dedicated inspection and testing seal of Shanghai Research Institute of Chemical Industry Testing Co., Ltd.and QR Code on it.
2. 鉴定书复印件无效。
   Copies of the certification are invalid.
3. 鉴定书无主检、审核、批准签字无效。
   The certification is invalid without the signatures of appraiser, checker and approver.
4. 鉴定书涂改无效。
   The certification is invalid if it is forged or altered.
5. 委托单位必须保证送至本公司的样品及资料与真实的出运货物相一致，如有不符，所涉及的法律责任及其他后果均由委托单位自行承担。
   The client must guarantee that samples and documents provided for appraisal are consistent with the goods to be transported. Otherwise, the client shall bear all legal responsibilities and other consequences due to it.
6. 本鉴定书的鉴定结论仅适用于最终收到的样品。
   The conclusion of this certification only applies to the final sample as received.
7. 本鉴定书当年有效，铁路运输方式除外。特殊情况参见鉴定书备注。
   The certification is valid in the year subscribed on it except when transported by rail. Please refer to the comment of certification on special occasion.
8. 本鉴定书不考虑国家及经营人差异。
   The certification takes no account of the State and Operator Variations.
9. 货物的运输方式应与鉴定结论中的运输方式相一致。不同的运输方式，鉴定结果可能会有差异。
   The transportation mode of the goods shall be consistent with that in the appraisal conclusion. Different transportation modes may lead to different appraisal results.
10. 鉴定书真伪性可登入本公司网站 www.ghs.cn 或扫描鉴定书中二维码进行查询。
    The authenticity of the certification can be verified by our website(www.ghs.cn)or the QR code in the certification.
11. 送检申请可登入本公司网站 www.ghs.cn 进行网上委托。
    The application of the certification can be done via our website: www.ghs.cn.

地址：上海市光复西路2779号接待大厅
Address: Reception Hall, Shanghai Research Institute of Chemical Industry Co., Ltd, No.2779 West Guangfu Road, Shanghai, China.
邮编(Post code): 200062
电话(Tel):(008621)31765555
邮箱(Email): center@ghs.cn
网址(Website): www.ghs.cn

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020158798

样品名称 Sample Name	中文 Chinese	新型冠状病毒IgM/IgG抗体检测试剂盒 （胶体金法）
	英文 English	SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
委托单位 Consignor		湖南康润药业股份有限公司
生产单位 Manufacturer		湖南康润药业股份有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		白色纸盒（内含无色透明液体和白色塑料试剂板），稍有气味 White Paper box(containing colorless transparent liquid and white plastic reagent board), Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。
None.

2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR)

可按非限制性货物条件办理。
The substance is not subject to IATA DGR.

3. 包装要求(Packaging requirements)

无。
None.

检验日期: Inspection Date: 2020-03-31 签发日期: Issue Date: 2020-04-01 生效日期: Effective Date: 2020-04-01

备注 Comment	无。 None.

批准 Approver: 审核 Checker: 主检 Appraiser:

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020158798

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
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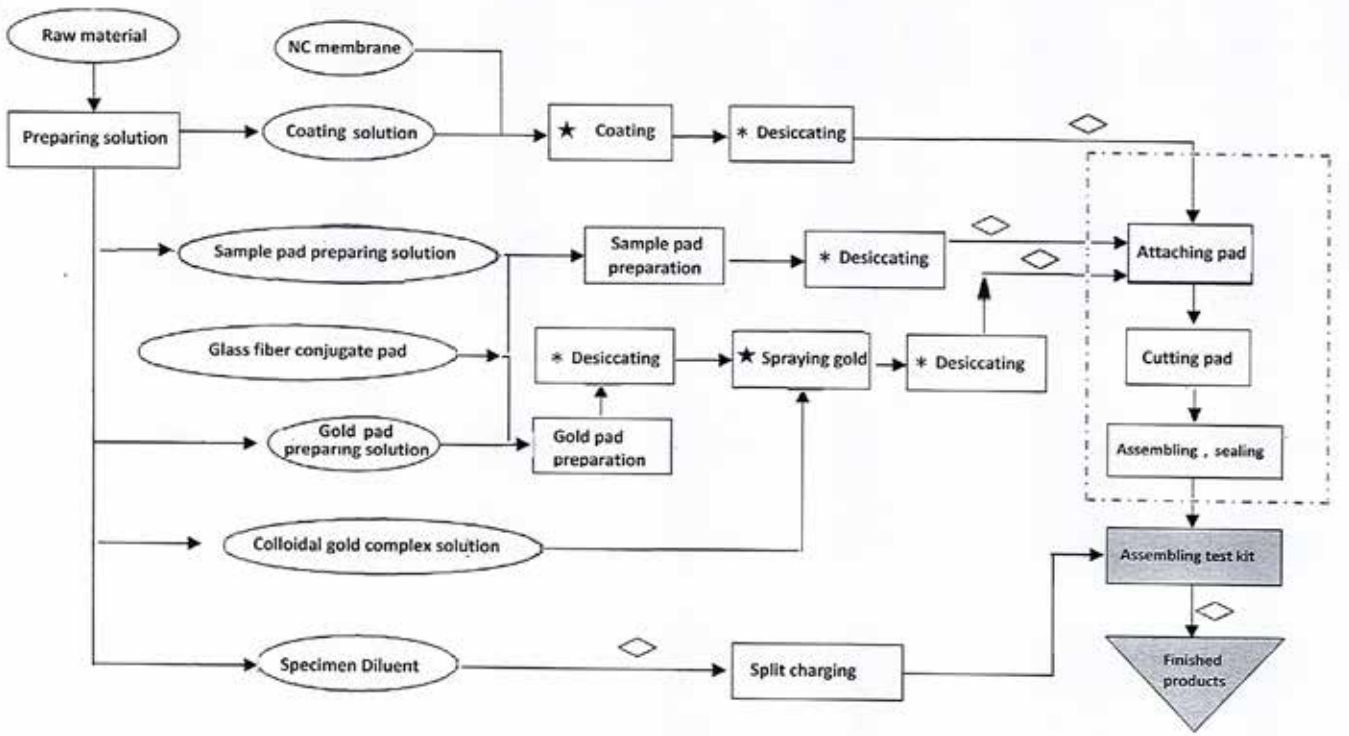
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:219826-

报告结束

SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)
Manufacturing Flow Chart



Hunan Ranken Pharmaceutical Co., Ltd.

PROTC LIFE®

Hunan RunKun Pharmaceutical Co., Ltd.
N0.380 Baling East Road, Economic-Technological Development Zone,
Yueyang, Hunan,414000, P.R.China
Tel:+86-730-8725966, Fax:+86-730-8725900

EU Declaration of Conformity

Manufacturer: Hunan Runkun Pharmaceutical Co., Ltd.
Address: N0.380 Baling East Road, Economic-Technological Development Zone, Yueyang, Hunan,414000, P.R.China
European representative: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Medicines and Healthcare Products Regulatory Agency
Competent Authority NL (CIBG)

Herewith declare that the attached listed products meet the applicable provisions of the EU Directive 98/79/EC on in vitro diagnostic medical devices for other classes, and carry the CE mark accordingly.

Mao Jinwu

Mao Jinwu (Authorized Signatory)

General Manager

For and on behalf of

Hunan Runkun Pharmaceutical Co., Ltd.

Place: Yueyang,Hunan,P.R.China Date: 18-March-2020

Hunan RunKun Pharmaceutical Co., Ltd.
N0.380 Baling East Road, Economic-Technological Development Zone,
Yueyang, Hunan,414000, P.R.China
Tel:+86-730-8725966, Fax:+86-730-8725900

Product Information

product group	Productname	Product Description
1	SARS-CoV-2 IgM/IgG Test Kit(Colloidal Gold)	This kit is based on the principle of colloidal gold immunochromatography for determination of SARS-CoV-2 IgG/IgM antibodies in human serum, plasma and whole blood specimens. This kit is consist of test card and specimen diluent（0.9%NaCl solution）.

PROTC LIFE®

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20200779

Bijlagen
-

Uw aanvraag
20 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 26 maart 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 20 maart 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Hunan RunKun Pharmaceutical Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-49830)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Hunan RunKun Pharmaceutical Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

PROTC LIFE ®

QQ邮箱 mail.qq.com

RE: registratie certificaat.

发件人：medische_hulpmiddelen<medische_hulpmiddelen@minvws.nl>
时　间：2020年4月2日(星期四) 下午5:53
收件人：猛醒十分<30223994@qq.com>

Geachte Wu Gangqiang,

Hierbij bevestig ik dat wij de administratieve bevestiging van onderstaand producten hebben verzonden.

Vanaf 26 mei 2020 geldt nieuwe EU-wetgeving voor medische hulpmiddelen (MDR). En per 26 mei 2022 voor in vitro diagnostica (IVDR). Dit heeft gevolgen voor o.a. fabrikanten en gemachtigden van niet EU-fabrikanten.

Voor meer info zie https://www.farmatec.nl/medische-hulpmiddelen/nieuws/2020/03/10/nieuwe-eu-wetgeving-per-26-mei-2020

Met vriendelijke groet,

Mw. T. van Langeveld – Baas
Behandelaar

.....

Medische Hulpmiddelen

Agentschap CIBG | Uitvoeringsorganisatie van VWS

Rijnstraat 50 | 2515 XP | Den Haag

Postbus 16144 | 2500 BC | Den Haag

.....

Tel. 070-3406161

medische_hulpmiddelen@minvws.nl

www.farmatec.nl

Van: 猛醒十分 <30223994@qq.com>
Verzonden: donderdag 2 april 2020 03:30
Aan: CIBG Medische Hulpmiddelen <medische_hulpmiddelen@minvws.nl>
Onderwerp: registratie certificaat.

Beste CIBG-team,

Wij zijn Hunan Runkun Pharmaceutical Co., Ltd. van de fabrikant van SARS-CoV-2 IgM / IgG-testkits (colloïdaal goud). We hebben lotus NL B.V. de opdracht gegeven om het kentekenbewijs aan te vragen.

En we hebben een notificatie e-mail ontvangen van Lotus NL B.V., maar we hebben geen ondertekende certificering ontvangen, kunt u ons controleren of het echt of nep is? De onderstaande informatie,

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
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http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langevelt - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20200779

Bijlagen
-

Uw aanvraag
20 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 26 maart 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 20 maart 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Hunan RunKun Pharmaceutical Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-49830)

Bedankt voor je tijd en je snelle reactie wordt zeer op prijs gesteld.

Vriendelijke groeten,

Wu Gangqiang

Hunan Runkun Pharmaceutical Co., Ltd.

PROTC LIFE®

No.202001957

河南省医疗器械检验所

检验检测报告

产品名称：新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）

检验类别：委托检验

委托方：湖南康润药业股份有限公司

PROTC LIFE®

声 明

一、本检验检测报告仅对我单位接收到的样品负责。

二、本检验检测报告涂改增删无效，无“检验检测报告专用章”无效，无批准人签字无效。

三、复制报告未重新加盖检验机构检验检测报告专用章或检验单位公章无效。

四、本检验检测报告一式三份，二份交送检单位，一份由我单位存档。

五、对检验检测报告若有异议，应于规定期限内向我所提出书面申诉意见，逾期未提出异议的，视为认可检验检测结果。

六、未加盖CMA章的检验检测报告，仅用于医疗器械产品注册。

PROTC LIFE®

河南省医疗器械检验所

检验检测报告首页

报告编号：202001957

样品编号：委20200844

样品名称	新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）	样品数量	9盒
	送样（ ） 抽样（√）	规格型号	20人份/盒
委托方	湖南康润药业股份有限公司		
生产地址	湖南省岳阳市经济技术开发区巴陵东路	生产批号	20200201
		生产日期	2020年02月25日
标示生产单位	湖南康润药业股份有限公司	产品编号	/
受检单位	湖南康润药业股份有限公司	有效期	2020年8月24日
抽样单位	湖南省药品监督管理局	检验类型	委托检验
库存数量	63盒	样品状态	正常
抽样日期	2020.04.16	收样日期	2020.04.17
抽样地点	成品库	检验地点	本检验所试验室
抽样单编号	0001018	检验日期	2020.04.20-2020.04.21
检验项目	全项目		
检验依据	湖南康润药业股份有限公司《新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）》产品技术要求		
检验结论	被检样品符合湖南康润药业股份有限公司《新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）》产品技术要求的要求。 签发日期：2020年04月21日		
备注	1)报告中的“——”表示此项不适用，报告中“/”表示此项空白或未检。		

报告批准：

报告审核：

检　　验：

PROTC LIFE®

河南省医疗器械检验所

检验检测报告

样品编号：委20200844

新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）				
检验项目	标准条款	标准要求	检验结果	单项结论
外观	2.1	试剂盒外包装完整，标签清晰，组分齐全；卡壳完整无压坏，检测窗口NC膜无划痕及污渍；液体试剂组分无浑浊。	符合要求	合格
膜条宽度	2.2	应不小于2.5mm。	3.0mm	合格
移行速度	2.3	液体移行速度应不低于10mm/min。	23mm/min	合格
阴性参考品符合率	2.4	15份企业阴性参考品检测，阴性符合率应为15/15。	IgM：均为阴性，15/15 IgG：均为阴性，15/15	合格
阳性参考品符合率	2.5	用10份企业阳性参考品检测，P1-P4应为IgM和IgG阳性，P5-P7应为IgM阳性和IgG阴性，P8-P10应为IgM阴性和IgG阳性，阳性符合率应为10/10。	P1-P4，IgM：均为阳性，IgG：均为阳性 P5-P7，IgM：均为阳性，IgG：均为阴性 P8-P10，IgM：均为阴性，IgG：均为阳性 阳性符合率：10/10	合格
最低检测限	2.6	用企业检测限参考品检测，L1-L3应为IgM和IgG阳性，L4应为阴性。	L1-L3，IgM：均为阳性，IgG：均为阳性 L4：IgM：阴性，IgG：阴性	合格
重复性	2.7	用企业重复性参考品J1、J2各重复检测10次，J1、J2应为IgM和IgG阳性。	J1，IgM：均为阳性，10/10；IgG：均为阳性，10/10 J2，IgM：均为阳性，10/10；IgG：均为阳性，10/10	合格
装量	2.8	应不少于标示值（5ml）。	5ml	合格
备注： 以下空白				