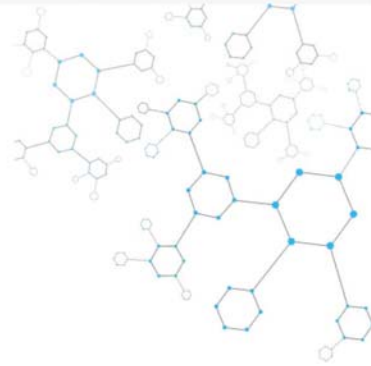


## Advantages



### Rapid

Test results in only 10 minutes. Results can be read by naked eyes

### Easy

Easy to operate, suitable for fingerstick sample, serum, plasma and whole blood

### Combined

Test both IgM and IgG antibodies

### Convenient

Stored at room temperature  
All required accessories are provided in the test kit

## Applications



Community



Medical institution



Airport/Station



School

# CFDA certificate

**医疗器械生产许可证**

许可证编号: 粤食药监械生产许 20162884 号

企业名称: 海格德生物科技(深圳)有限公司  
生产地址: 深圳市坪山新区大工业区青松路56号友利通科技工业厂区A栋  
801、深圳坪山新区金碧路14号深圳市生物医药创新产业园区  
号楼604号

法定代表人: 贺新华  
生产范围: 见医疗器械生产许可证


企业负责人: 贺新华

住 所: 深圳市坪山新区大工业区青松路56号友利通科技工业厂区A栋801  
发证部门: 广东省药品监督管理局

有效期限: 至 2021 年 10 月 23 日 发证日期: 2019 年 01 月 30 日

国家食品药品监督管理总局制

# ISO 13485



REGISTRATION NO. 04717Q1000055


**CERTIFICATE OF QUALITY MANAGEMENT  
SYSTEM FOR MEDICAL DEVICES**

This is to certify that the quality management system of  
**H-Guard (China) Co., Ltd.**  
Registered Address: 801, Bldg.A, 56 Qingsong Rd., Pingshan, Shenzhen,  
Guangdong, China Postcode: 518118  
Manufacturing Address: 801, Bldg.A, 56 Qingsong Rd., Pingshan,  
Shenzhen, Guangdong, China

Has been assessed and conformed to the following standard(s)  
**YY/T 0287-2003 idt ISO 13485:2003**

The certificate is valid for the following scope:  
The Design, Development, Production and Service of Human  
High Sensitivity C-Reactive Protein (hs-CRP) Assay Kit (ELISA),  
Human Lipoprotein-Associated Phospholipase A<sub>2</sub> (Lp-PLA<sub>2</sub>) Assay Kit  
(ELISA), Human Myeloperoxidase (MPO) Assay Kit (ELISA),  
Human N-Terminal proBNP (NT-proBNP) Assay Kit (ELISA).

Date of issue: February 17, 2017  
Date of expiry: March 01, 2021

Director: 

**BEIJING HUA GUANG CERTIFICATION  
OF MEDICAL DEVICES CO., LTD.**

Note: The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)) or the Website of CMD ([www.cmdc.com.cn](http://www.cmdc.com.cn)).  
Add: 5<sup>th</sup> floor of Zhong Lian Building, No.1488, An Ding Men Wai Dajie, DongCheng District, Beijing, 100011, CHINA TEL: 010-62351993

CE

File No: CE-TCF-001

**CE Declaration of Conformity**

**Regarding In Vitro Diagnostic Directive (98/79/EC)**

**Manufacturer:**  
Name: H-Guard (China) Co., Ltd.  
Address: 6th Floor, Building B1, No.14, Jinhui Rd., Pingshan, Shenzhen, China

**EC Representative**  
Name: SUNGO Europe B.V.  
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product**  
Name: Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)  
Type: 20 tests/box  
Classification: IVDD Others

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 14971:2012  
EN 15223-1:2016  
EN ISO 18113-1:2011  
EN ISO 18113-3:2011

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

**Signature:**  *Authorized Signature (S)*

**Date:** 3-22-2020



Medical product export Certificate

# 深圳市医疗器械行业协会

中华人民共和国  
PEOPLE'S REPUBLIC OF CHINA

## 医疗器械产品出口销售证明书 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: SAMD2020-031  
Certificate No.: SAMD2020-031

产品名称: 新型冠状病毒 COVID-19 IgM/IgG 抗体检测试剂盒 (胶体金法)  
Product(s): Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)

规格型号: 20 人份/盒  
Model No: 20 tests/box

生产企业: 海格德生物科技(深圳)有限公司  
Manufacturer: H-Guard (China) Co., Ltd.

生产企业地址: 深圳市坪山区坑梓街道金沙社区金辉路 14 号深圳市生物医药创新产业园区 1 号楼 604  
Address of manufacturer: 6th Floor, Building B1, No.14, Jinhui Rd., Pingshan, Shenzhen, China

出口企业: 海格德生物科技(深圳)有限公司  
Distributor: H-Guard (China) Co., Ltd.

出口企业地址: 深圳市坪山区坑梓街道金沙社区金辉路 14 号深圳市生物医药创新产业园区 1 号楼 604  
Address of distributor: 6th Floor, Building B1, No.14, Jinhui Rd., Pingshan, Shenzhen, China

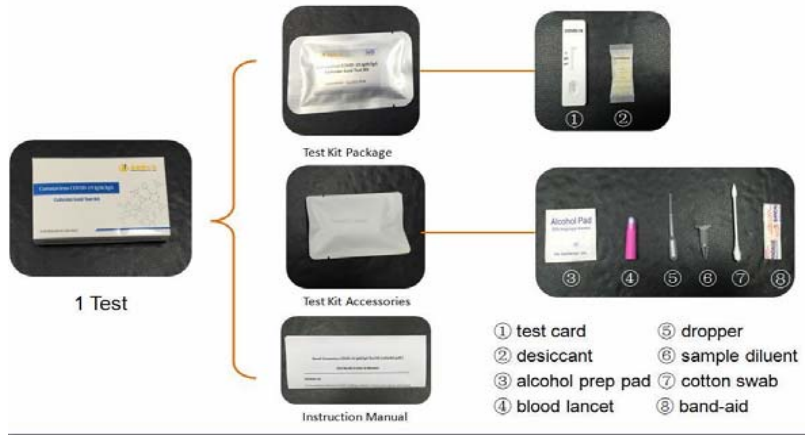
深圳市医疗器械行业协会  
Shenzhen Association of Medical Devices  
2020年3月31日  
Issuing date: March 31, 2020



(此证书从发证时起有效期 2 年)

(This certificate is valid for two years from the date of issuance)

# 1) Full package(include accessory)



20 tests/box, 30 boxes/carton, total 600 tests/ carton

Carton size:65x41x49 CM Gross weight:19.5KG

# 2) Compact package(without accessory)



40 tests/box,50 boxes/carton, total 2000 tests/ carton

Carton size:65x41x49 CM Gross weight:19KG

# Air cargo safety report

中国认可  
 检验  
 INSPECTION  
 CNAS IB0078

**非限制性货物**  
**NOT RESTRICTED**

航空运输条件鉴别报告书

Identification and Classification Report for Air Transport of Goods

此报告本年度有效  
 有效期至2020年12月31日

报告编号: PEKSZ202004021568ZY420001  
 Issued No.:  
 签发日期: 2020.04.20  
 Issued Date:  
 委托单位: 海格德生物科技(深圳)有限公司  
 Applicant: H-Guard (China) Co., Ltd.  
 物品名称: 新型冠状病毒(COVID-19) IgM/IgG抗体检测试剂盒(胶体金法)  
 Name of Goods: Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)  
 北京油捷航空技术开发有限公司