

# 中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products  
A48 11-13/F, Bldg A, Beijing 100151, No. 83 Huangpu Road, Guangzhou District, Beijing, China P.C. 100018  
Tel: 86(0)10 58106272/51317170 Fax: 0086 10 58106274 Website: www.cccmhp.org.cn  
E-mail: 11088227@ccmhp.com 82379517@qq.com info@ccmhp.org.cn



## 自由销售证书

### CERTIFICATE OF FREE SALE

2621Y180095

产品名称: 见附件  
Product(s): SEE ATTACHMENT

规格型号: 见附件  
Models: SEE ATTACHMENT

品牌: Longsee  
BRAND: Longsee

销往国家: 德国  
Export to: Germany

出口商: 广东南芯医疗科技有限公司  
Exporters: Guangdong Longsee Biomedical Co., Ltd.

出口商地址: 广东省广州市黄埔区瑞和路 83 号 A 栋 5 楼  
Address: 5th Floor, Building A, No. 83 Ruihe Road, Huangpu District, Guangzhou City, China

制造商: 广东南芯医疗科技有限公司  
MANUFACTURER: Guangdong Longsee Biomedical Co., Ltd.

制造商地址: 广东省广州市黄埔区瑞和路 83 号 A 栋 5 楼  
ADDRESS: 5th Floor, Building A, No. 83 Ruihe Road, Huangpu District, Guangzhou City, China

兹证明上述产品符合相关标准, 未在中国注册, 该产品出口不受限制。

THIS IS TO CERTIFY THAT THE ABOVE PRODUCT COMPLIES WITH THE RELEVANT STANDARDS, HAVE NOT BEEN REGISTERED IN CHINA. THE EXPORTATION OF THE PRODUCT IS NOT RESTRICTED.

此证明自签发时起有效期 2 年。

THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会  
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF  
MEDICINES & HEALTH PRODUCTS  
证明日期: 2021 年 5 月 6 日  
DATE OF ISSUE: May 6, 2021

## DECLARATION OF CONFORMITY

**Manufacturer** Guangdong Longsee Biomedical Co., Ltd.  
**Address** 5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China  
**European Representative Address** MedPath GmbH  
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany  
**Product Information** 2019-eCoV Ag Rapid Detection Kit (Immuno-Chromatography)  
**Model code** LS-C-T-009  
**Classification** Other IVD Device  
**Registration Number in German DIMDI Database** DE:CA61/1M50/294  
**Conformity Assessment Route: Annex III**

**General Applicable Directives** In vitro diagnostic medical devices Directive: 98/79/EC  
**Standards Applied** EN 13612:2002/AC: 2002 EN ISO 13485:2016  
EN ISO 23640:2015 EN ISO 14971:2012  
EN 13641:2002 EN ISO 18113-1:2011  
EN 15223-1:2016 EN ISO 18113-2:2011

We, the manufacturer, hereby declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. The products meet prospective uses and all supporting documentations are retained under the premises of the manufacturer.

Place, date of issued: Guangzhou, P. R. China, May 10, 2021  
Signature of Vice President:

(Marco Zhang)

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