[redacted]

COVID-19 AT-HOME TEST KIT

[redacted] is manufacturing a COVID-19 At-Home Test Kit through its China supplier. Below are several details on the product being produced.

1. The suppy is being sourced from one of our suppliers that produces various medical supplies. The COVID-19 At-Home Test Kit has been added to their group of products and allows individuals to perform an at-home test with results in just 15 minutes.

2. Our source has worked closely with the Chinese public to develop this test kit.

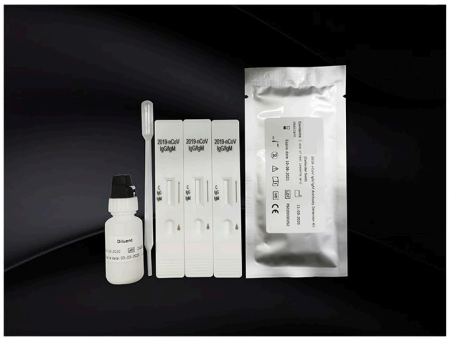
3. COVID-19 At-Home Test Kits have recently been praised by the World Heath Organization (WHO) for its effectiveness in testing for the Coronavirus.

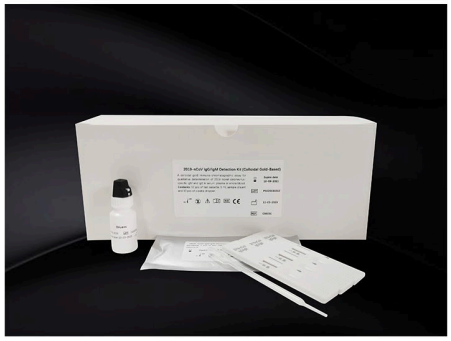
4. Our factory has all the necessary approvals from the Chinese Government and has been certified by the European Union Parliament to supply this product. This includes supplying the COVID-19 Test Kits, to Europe and other countries around the world.

5. Our source, has received the China Food and Drug Administration (CFDA) approval, a requirement that must be met to receive Food and Drug Administration (FDA) approval.

6. Presently our supplier has a capacity of 500,000 units per day. Additional shifts can be added to increase their current production capacity.

[redacted]





[redacted]

[redacted]

EC Declaration of Conformity

Manufacturer:

[redacted]

European Representative:

[redacted]

Product Name: 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into nationallaw,the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

Signature: [redacted]

Name: [redacted]
Position: [redacted]
Place: [redacted]
DateofIssue: 28th,Feb, 2020

[redacted]

CE

[redacted]

EC Declaration of Conformity

Manufacturer:

[redacted]

European Representative:

[redacted]

Product Name: 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)
Model: Cassette / Dipstick
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into nationallaw,the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

Signature: [redacted]

Name: [redacted]
Position:
Place: [redacted]
Dateofissue: 24th Feb, 2020

[redacted]

CE

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. [redacted]

Holder of Certificate: [redacted]

Facility(ies): [redacted]

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In-vitro Diagnostic Test Kits based on Latex Particle-enhanced Turbidimetric Immunoassay and Quantum Dot Immunofluorescence Assay, Dry-type Fluorescence Immunity Analyzer**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: [redacted]

Valid from: 2018-05-09

Valid until: 2021-05-08

Date, 2018-05-09

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

The People's Republic of China
Registration Certificate for Medical Device
(In Vitro Diagnostic kit)

Reg. No.: National Medical Device Registration Standard: [redacted]

Registrant	[redacted]
Registrant Address	[redacted]
Manufacture's Address	[redacted]
Name of Agent	/
Agent Address	/
Product Name	2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based).
Packing Specification	10 droppers /pack, 20 droppers /pack, 25 droppers /pack, 30 droppers / pack, 40 droppers /pack, 50 droppers/pack.
Major Ingredient	Test strip, specimen dilution, dropper. (See user instruction for details)
Intended Use	This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). It is suitable for qualitative detection of IgG / IgM antibodies in human serum, plasma, and whole blood.
Attachment	Product technical requirement, user instruction
Storage Condition and Term of Validity	Store at 4 to 30°C. The shelf life is temporarily set as 6 months.
Other Terms	/
Remarks	Post-marketing work shall be completed as follows: 1. This product is only used as assistant diagnoses and emergency stock for Coronavirus (SARS-CoV-2), and the validity of this Registration Certificate is only one year. 2. Renewal of the Registration Certificate shall submit summary report of clinical application data in compliance with following requirements: collection of ongoing clinical application data from more than three clinical medical institutions including Centers for Disease Control and Prevention at all levels. Sufficient information shall be contained in the clinical application data, sample size shall conform to statistical requirements and signature and stamp also shall comply with requirements.sample capacity and signature stamp must meet relevant requirements. 3. Manufacturer shall complete all registration documents in compliance with the registration requirements for in vitro diagnostic kit.

Approval department: National Medical Products Administration

Approval Date: 13th March, 2020
Expiry Date: 12th March, 2021

中华人民共和国

医疗器械注册证（体外诊断试剂）

注册证编号：国械注准[redacted]

注册人名称	[redacted]
注册人住所	[redacted]
生产地址	[redacted]
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）IgM / IgG抗体检测试剂盒（胶体金法）
包装规格	10人份/盒，20人份/盒，25人份/盒，30人份/盒，40人份/盒，50人份/盒。
主要组成成分	检测卡、样本稀释液、吸滴管。（具体内容详见产品说明书）
预期用途	本试剂盒用于体外定性检测人血清、血浆样本中新型冠状病毒（2019-nCoV）IgM/IgG抗体。仅用作对新型冠状病毒核酸检测阴性疑似病例的补充检测指标或疑似病例诊断中与核酸检测协同使用，不能作为新型冠状病毒感染的肺炎确诊和排除的依据，不适用于一般人群的筛查。 该产品仅限医疗机构使用。
附件	产品技术要求、说明书
产品储存条件及有效期	试剂盒于4～30℃，有效期暂定6个月。
其他内容	/
备注	上市后进一步完成以下工作： 1. 本产品仅为新型冠状病毒（2019-nCoV）感染的肺炎的辅助诊断及应急储备，注册证有效期为一年。 2. 延续注册时应按照如下要求提交临床应用数据的总结报告：应在三家以上临床医疗机构（包括各级疾病预防控制中心）收集该产品连续临床应用数据。临床应用数据应具有完善的信息，样本量符合统计学要求，签字盖章符合要求。 3. 企业应当延续注册时按照体外诊断试剂注册管理办法的要求完善所有注册申报资料。

审批部门：国家药品监督管理局

批准日期：二〇二〇年三月十三日

有效期至：二〇二五年三月十二日