普迈德（北京）科技有限公司

Pro-med (Beijing) Technology Co.,Ltd

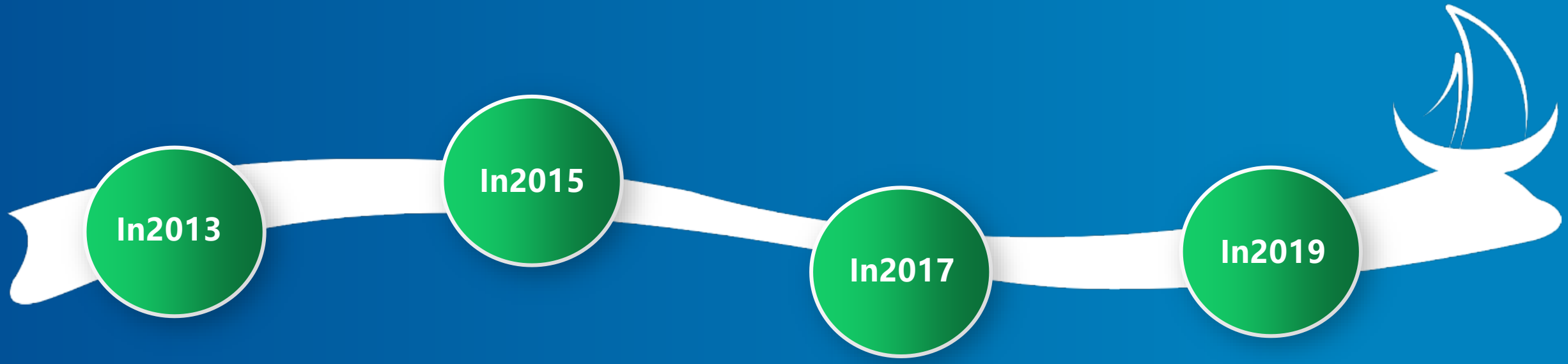
Pro-med technology 普迈德

- Company Overview
- Enterprise Qualification & honor
- Production Capacity
- COVID-19 Antigen Rapid Test

Company Overview

- Pro-med established in 2013 which has two production, R&D bases in Beijing’ s Zhongguancun Science and Technology Park and Jiangsu China Medical City, 30 independent intellectual property rights, and 80 conventional product lines.
- More than 10,000 m^2 production area, 300 employees, the daily production capacity exceeds 3 million.
- self-produced core IVD raw materials.
- Pro-med have obtained CE certificates and China whitelists, Germany BfArM, Italian approval and Austrian BASG.
- The self-test list of France, Netherlands, Denmark, Austria and other countries are in application.

Milestone



pro-med was founded, focusing on rapid diagnosis

Entered into the POCT market,
At present, the business has covered 8000+ medical institutions

Set up a wholly owned subsidiary, Jiangsu Aoya Biotechnology Co., Ltd

Entered into the international market. Business coverage of Germany, France, the Netherlands, Denmark, Austria....

Service

- Include 80+ Clinical Test Items
- Serve 8,000+ Medical Institutions
- Safeguard Health of 100,000,000 People

7 Technology Platforms

- Immune Colloidal Gold Platform
- Immunofluorescence Platform
- Diagnostic platform for bleeding/coagulation
- Chemiluminescence Platform
- Molecular Diagnostics Platform
- Instrument Platform
- Biological Raw Material Platform

product Qualification & honor

Chinese Certificates

Business license | Produce license | ISO 13485:2016

编号：I 03516612

营业执照

(副本) (1-1)

统一社会信用代码 91110114078587382R

名称	普迈德（北京）科技有限公司
类型	有限责任公司(自然人投资或控股)
住所	北京市昌平区马池口镇昌流路738号8#楼三层C区
法定代表人	余占江
注册资本	1176.4706万元
成立日期	2013年08月29日
营业期限	2013年08月29日 至 2063年08月28日
经营范围	技术推广；生物制品技术开发、技术服务；货物进出口、技术进出口；生产临床检验分析仪器以及临床诊断器械；生产第二类、第三类医疗器械。（企业依法自主选择经营项目，开展经营活动；生产临床检验分析仪器以及临床诊断器械、生产第二类、第三类医疗器械以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

在线扫码获取详细信息

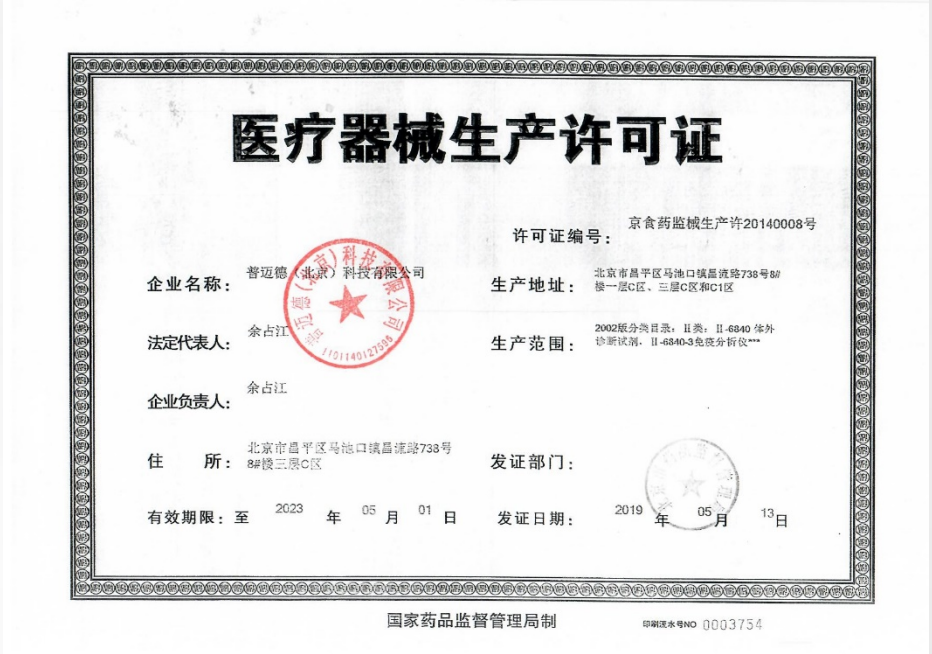
登记机关 北京市工商行政管理局昌平分局

2017年 10月 12日

提示：每年1月1日至6月30日通过企业信用信息公示系统报送上一年度年度报告并公示。

企业信用信息公示系统网址：qyxy.baic.gov.cn

中华人民共和国国家工商行政管理总局监制



医疗器械生产许可证

许可证编号：京食药监械生产许20140008号

企业名称：普迈德（北京）科技有限公司

生产地址：北京市昌平区马池口镇昌流路738号8#楼一层C区、三层C区和C1区

法定代表人：余占江

生产范围：2002版分类目录：II类：II-6840 体外诊断试剂，II-6840-3免疫分析仪***

企业负责人：余占江

住所：北京市昌平区马池口镇昌流路738号8#楼三层C区

发证部门：

有效期限：至 2023 年 05 月 01 日

发证日期：2019 年 05 月 13 日

国家药品监督管理局制

印刷泥水号NO 0003754

Global Certificates

European CE

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 via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20210327

Bijlagen
-

Uw aanvraag
22 januari 2021

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

Datum: 29 januari 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 22 januari 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Pro-med (Beijing) Technology Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

COVID-19 Antigen Rapid Detection Kit(Colloidal Gold),
COVID-19 Neutralizing Antibody Rapid Detection Kit(Colloidal Gold),
COVID-19 IgM/IgG Antibody Rapid Detection Kit(Colloidal Gold)
(geen merknaam) (NL-CA002-2021-55692)
Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit(Colloidal Gold),
COVID-19 and COVID-19 Mutant Strain(B.1.1.7 Strain)Antigen Rapid Detection Kit(Colloidal Gold)
(geen merknaam) (NL-CA002-2021-55693)

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

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen 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).

Pagina 1 van 2

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Pro-med (Beijing) Technology Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen 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

Pagina 2 van 2

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
Address: C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China
Tel:+86-10-57277459 **Website:**www.pmdt.com.cn

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We,Pro-med（Beijing）Technology Co., Ltd.,here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them.The declaration of conformity is exclusively under the responsibility of Pro-med（Beijing）Technology Co., Ltd.

Product Name	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

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Product Name	COVID-19 IgM/IgG Antibody Rapid Detection Kit(Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 IgM/IgG antibodies in human serum, plasma or whole blood samples.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

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Position Held In The Company	General Manager
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Product Name	COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 neutralizing antibodies in human serum, plasma or whole blood samples.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

Manufacturer:
Name: Pro-med （Beijing） Technology Co., Ltd.
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Product Name	Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit(Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the Influenza A+B and COVID-19 antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

EC Declaration of Conformity

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Tel:+86-10-57277459 **Website:**www.pmdt.com.cn

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Product Name	COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain) Antigen Rapid Detection Kit (Colloidal Gold)	**Specification**	One test/package; One test/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit
Intended Use	The kit is used for qualitative detection of the COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain) antigen in human nasopharyngeal or pharyngeal swab specimens.		
Classification	Others		

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

EN ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

Name Of Authorized Signatory	余占江
Position Held In The Company	General Manager
Signature	Yu Zhan Jiang
Date	February 5, 2021
Place	Beijing
Seal (Manufacturer)	

全球认证
Global Certificates

自由销售证明 | CFS

中国医药保健品进出口商会
China Chamber of Commerce for Import & Export of Medicines & Health Products

Add:11-12/F,Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010
Tel：0086 10 58036272/75/78/71/70 Fax：0086 10 58036274 Website：www.cccmhpie.org.cn
E-mail：110982739@qq.com 82579517@qq.com md@cccmhpie.org.cn

自 由 销 售 证 书

CERTIFICATE OF FREE SALE

2021YB1414

产品名称：COVID-19 新冠抗原快速检测试剂盒（胶体金法）
Product(s)：COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

产品名称：COVID-19 新冠抗体 IgM/IgG 快速检测试剂盒（胶体金法）
Product(s)：COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

产品名称：COVID-19 新冠中和抗体快速检测试剂盒（胶体金法）
Product(s)：COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)
规格型号：1 人份/袋、1 人份/盒、5 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒
Model ： 1 test/package;1 test/kit;5 tests/kit;10 tests/kit;20 tests/kit;25 tests/kit;30 tests/kit;40 tests/kit;50 tests/kit.

销往国家： 泰国
Export to: Thailand

买家：
Buyer: AD NANO CO., LTD.
地址：
Address: 36/1-6, Soi Ramkhamhaeng 24 Yaek 4 (Thawon Tawat 2), Hua Mak, Bang Kapi, Bangkok, 10240, Thailand.

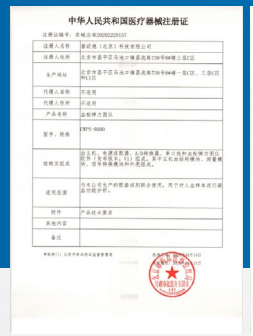
制造商：普迈德（北京）科技有限公司
Manufacturer：Pro-med (Beijing) Technology Co., Ltd.
地址： 北京市昌平区马池口镇昌流路 738 号 8 号楼三层 C 区，邮编 102202
Address: C-3F, 8#,738 Changliu Road, Machikou Town, Chang ping, 102202, Beijng, China.

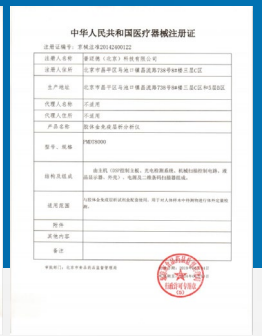
兹证明上述产品符合相关标准，未在中国注册，出口不受限制。
THIS IS TO CERTIFY THAT THE ABOVE PRODUCTS COMPLY WITH THE RELEVANT STANDARD HAVE NOT BEEN REGISTERED IN CHINA THE EXPORTATION OF THE PRODUCTS ARE NOT RESTRICTED.

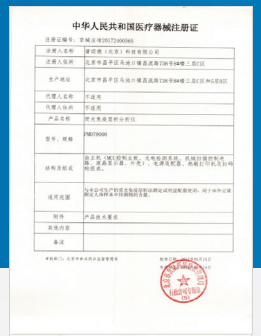
此证明自签发时起有效期 2 年。
THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

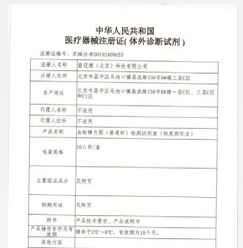
中国医药保健品进出口商会
CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS
证明日期：2021 年 7 月 8 日
DATE OF ISSUE: July 8, 2021

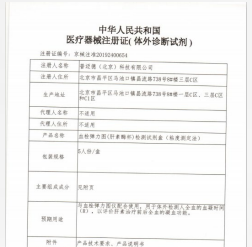
Awards & Honors

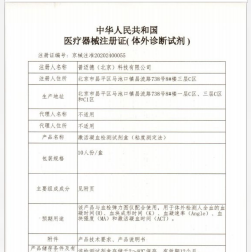


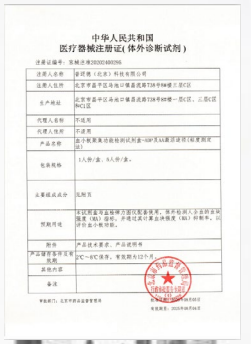












International Quality Management System &Authoritative Certification

Pro-med has established an international quality management system, strictly complying with international standards and regulations, including ISO 13485:2016, ISO 9001:2015, WHO, etc.

证书编号：04720Q10000330

医疗器械

质量管理体系认证证书

兹证明

（副本）

普迈德（北京）科技有限公司

（统一社会信用代码：91110114078587382R）

住　　所：北京市昌平区马池口镇昌流路 738 号 8#楼三层 C 区

生产地址：北京市昌平区马池口镇昌流路 738 号 8#楼一层 C 区、三层 C 区和 C1 区

质量管理体系符合：

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖：

胶体金免疫层析分析仪、荧光免疫层析分析仪和血栓弹力图仪的设计开发、生产和服务。

颁证日期：2020 年 08 月 15 日

有效期至：2023 年 08 月 14 日

总经理：

北京国医械华光认证有限公司

REGISTRATION NO. 04720Q10000330

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Beijing Pro-med Technology Co., Ltd.

Registered Address: C-3F, 8#, 738 Changliu Rd., Machikou Town, Changping District, Beijing

Manufacturing Address: C1, C-3F,C-1F, 8#, 738 Changliu Rd., Machikou Town, Changping District, Beijing

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of Quantitative Immunoassay Analyzer, Fluorescence Immunochromatorgraphi Analyzer and Thrombelastograph Instrument.

Date of issue: August 15,2020

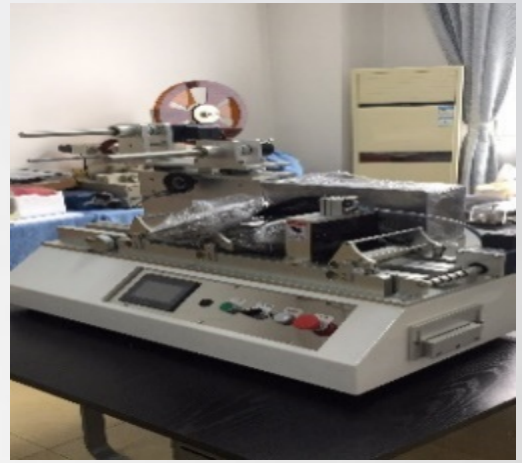
Date of expiry: August 14,2023

General Manager:

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

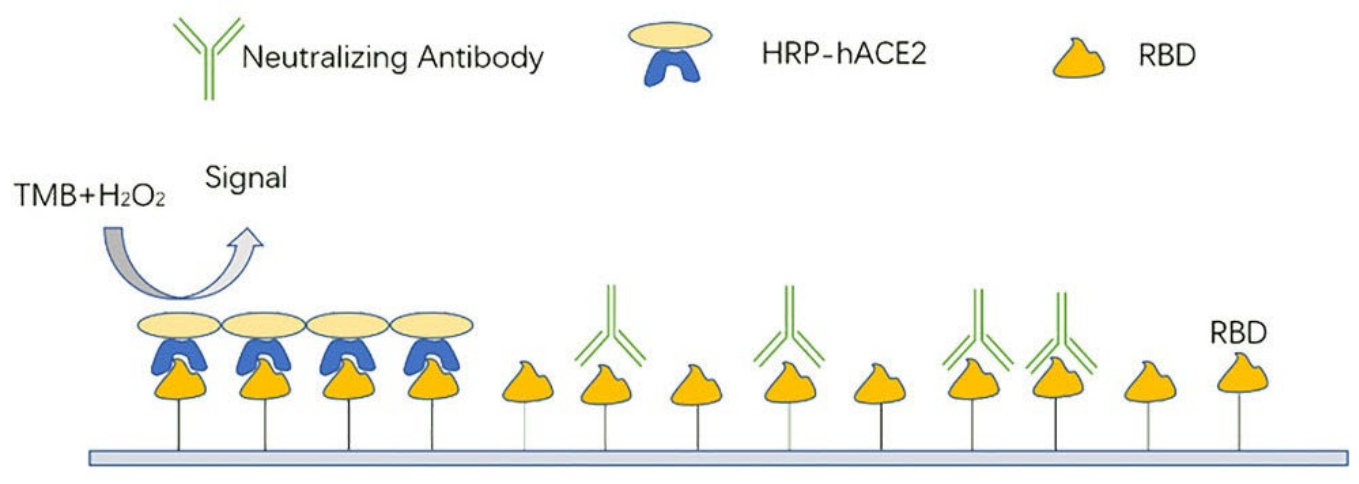
Production Capacity

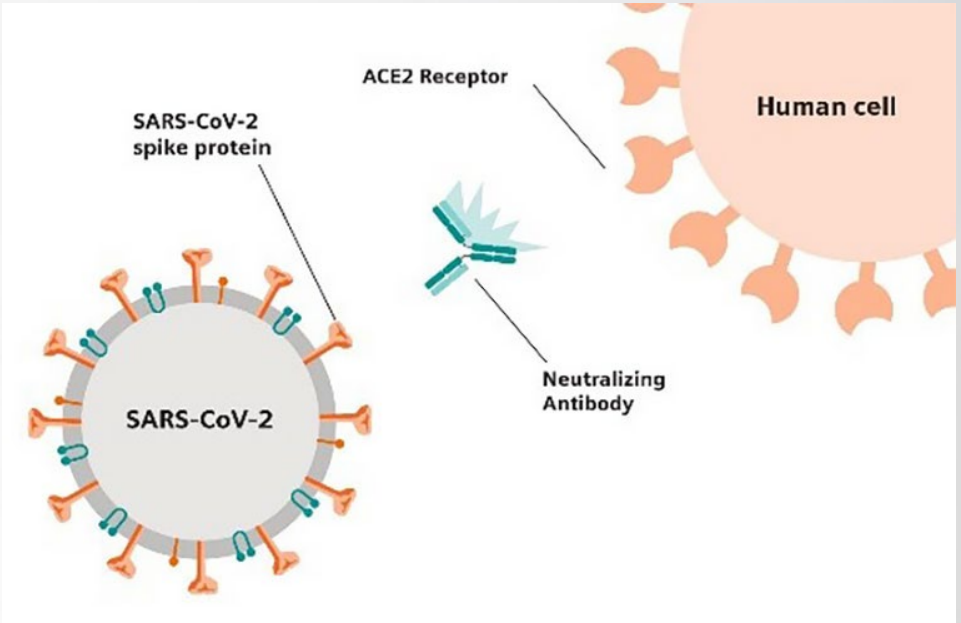
Mature production system and automated production line, Production capacity 3 million tests/day



COVID-19 Product Solution——neutralizing antibody Test

Neutralizing antibody test





Pro-med COVID-19 neutralizing antibody test kit

Professional Scenarios

CDC

Screening Scenarios

School

Professional Scenarios

Hospital

Screening Scenarios

Border

Screening Scenarios

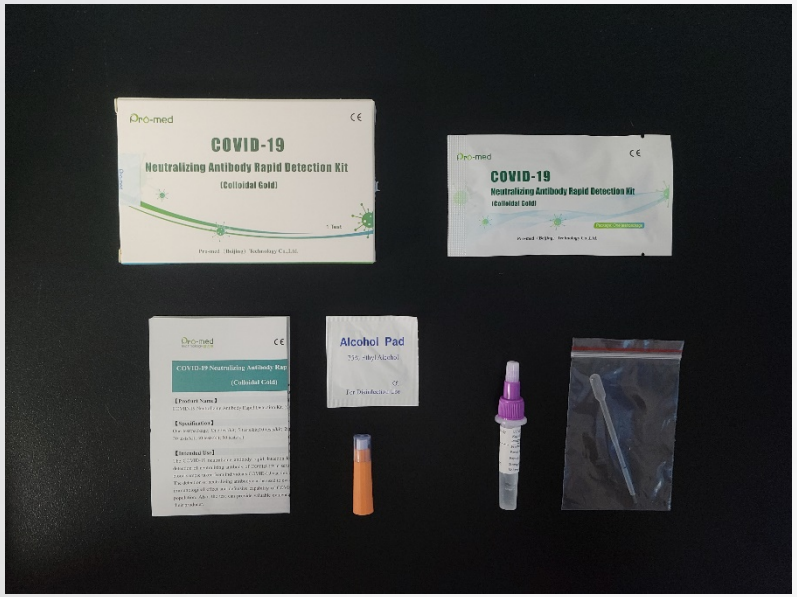
Factory

Test the antibody after vaccination, suit for most area, especially for selftest, this kind of test can be used for aiding in the diagnosis of COVID-19.

Applicabe sample types

COVID-19 neutralizing antibody test rapid test

Pro-med Covid-19 neutralizing antibody Rapid Test



- (1Test/Box) cassette

Box Size:

Length: 12.5cm

Width: 8cm

Height: 2.5cm

500 tests in box

Outside box:
52.5cm*52.5cm*44cm

Components:

1. Individual sealed pouches, each pouch contains:
   - 1×Test cassette
   - 1×Desiccant pouch
2. Single-use extraction buffer
3. Blood lancet
4. Alcohol pad
5. Blood collection
6. Instruction for use

Pro-med Covid-19 neutralizing antibody Rapid Test

- (20 Tests/Box)

Box Size:

Length: 17cm

Width: 12.5cm

Height: 7cm

1000 tests in box

Outside box:
38.5cm*38.5cm*67cm

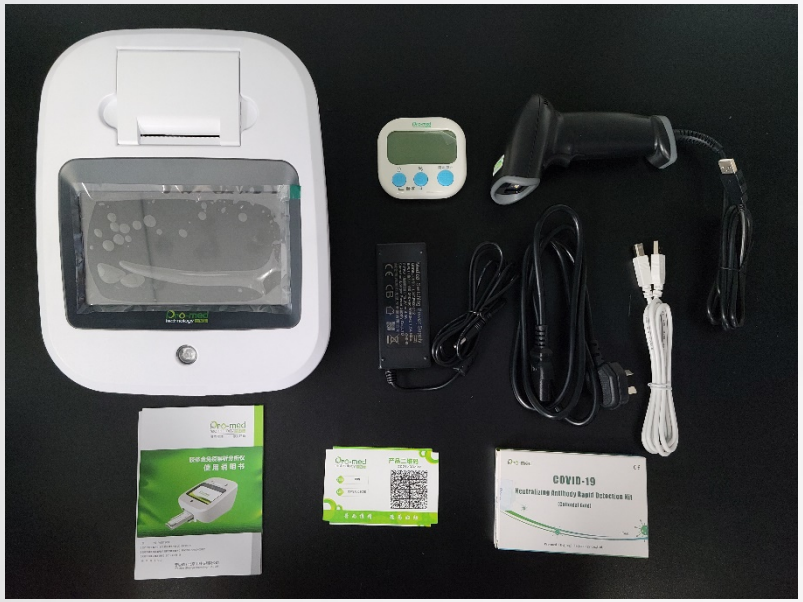
Components:

1. 20 Individual sealed pouches, each pouch contains:
   - 1×Test cassette
   - 1×Desiccant pouch
2. Extraction buffer(20)
3. 20 blood collection
4. 20 blood lancet
5. 20 alcohol pad
6. Instruction for use

* *Single-use extraction buffer can also be provided for 20 tests/box antigen test*

COVID-19 neutralizing antibody test rapid test

Pro-med Covid-19 neutralizing antibody quantitative Test



- (1/20 Test/Box) cassette
- PMDT 8000 analyzer

Components:

1. Machine
2. Clock
3. Scanner
4. Cable
5. Connection cable
6. IFU
7. Barcode
8. Test kit

Table：252 samples test results

Assessment reagent	ELISA		Total
	Positive(+)	Negative(-)	
Positive(+)	97	2	99
Negative(-)	5	148	153
Total	102	150	252

① Clinical sensitivity (positive coincidence rate)：

A/(A+C)×100%=95.10%

95% confidence interval: $p\pm1.96\times[\ p(1-p)/n]^{1/2}$=89.03%-97.89%

Clinical specificity (negative coincidence rate)：

D/(B+D)×100%=98.67%

95% Confidence interval: $p\pm1.96\times[\ p(1-p)/n]^{1/2}$=95.27%-99.63%

Overall coincidence rate：

(A+D)/ (A+B+C+D)×100%=97.22%

95% Confidence interval: $p\pm1.96\times[\ p(1-p)/n]^{1/2}$=94.38%-98.65%

② Consistency coefficient Kappa value（K)

$Kappa=(P_A-P_e)/\ (1-P_e)$

$P_A=(A+D)/\ (A+B+C+D)$= 0.9722

$P_e=[(A+B)\ (A+C)+(C+D)\ (B+D)]\ /(A+B+C+D)^2$

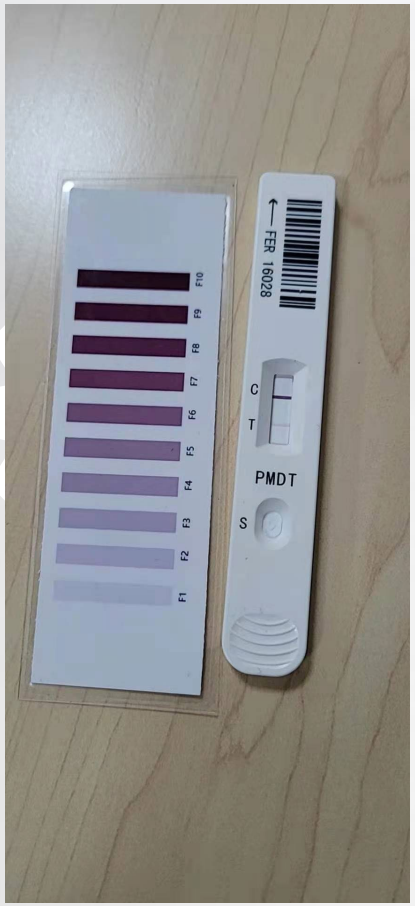
=0.5204

$Kappa=(P_A-P_e)/\ (1-P_e)$=0.9421

Kappa= 0.9421 (K>0.75)，it can be considered that the strength of agreement between the assessment reagent result and the nucleic acid test result is extremely high (K=0.9421 >0.75)

Clinic performance data

Pro-med Covid-19 neutralizing antibody quantitative Test



- Simple operation, no lab equipment requied
- Rapid test, instant results within 15mins
- Affordable price, reliable results
- high sensitivity and good specificity

Thanks for you watching

More details please further contact