普迈德（北京）科技有限公司
资质介绍

CERTIFICATES of Pro-med (Beijing) Technology Co., Ltd.

Pro-med technology 普迈德

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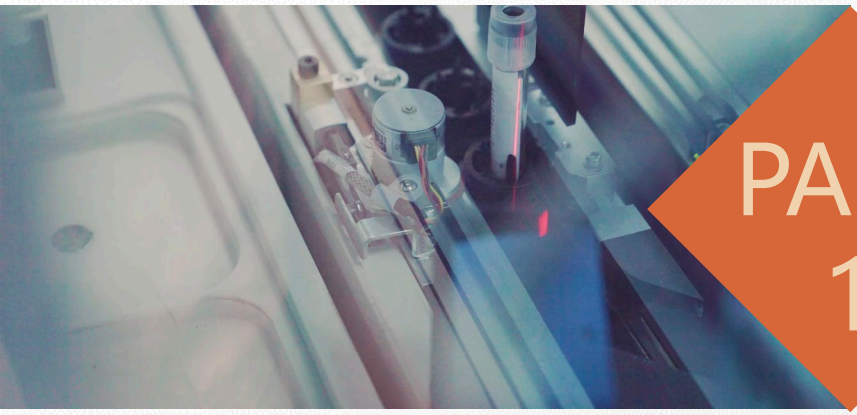
Tips: Click the name to see the certificates you interests



PART 1

国内认证

Chinese Certificates

国内证书
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。

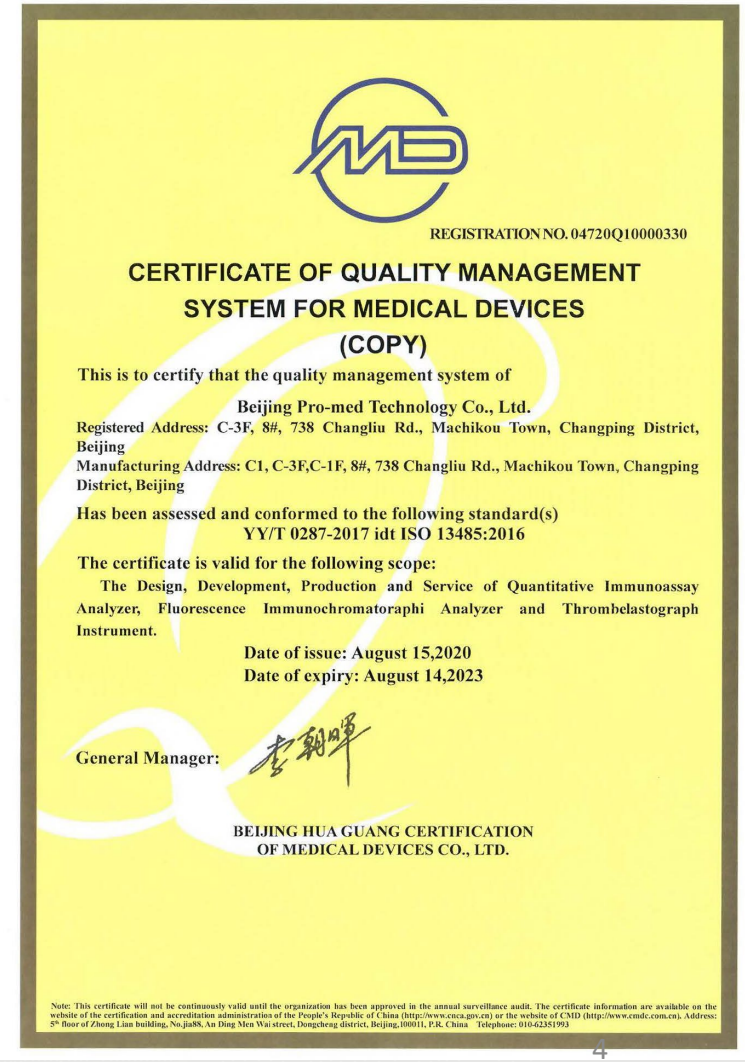
企业信用信息公示系统网址： qyxy.baic.gov.cn　　中华人民共和国国家工商行政管理总局监制

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　　印刷流水号NO 0003754



REGISTRATION NO. 04720Q10000330

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

(COPY)

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 Immunochromatoraphi 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.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

国内证书
Chinese Certificates

商务部白名单 | Chinese Whitelist

中国医药保健品进出口商会
服 务 产 业 链 | 助 力 国 际 化

English 登陆 | 注册

请输入关键词进行搜索

开具不可抗力相关事实性证明

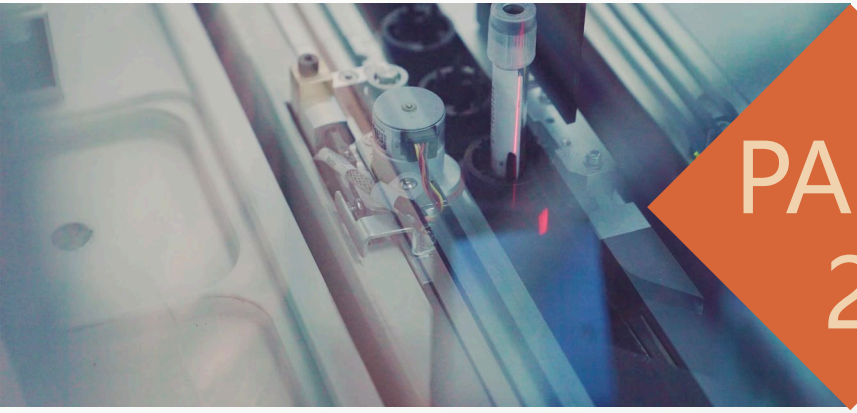
取得国外认证和注册企业查询

首页 | 关于商会 | 新闻中心 | 行业服务 | 权威发布 | 商会会刊 | 企业风采 | 会员之家 | 加入商会

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

普迈德 检索

企业名称（中文）	企业名称（英文）	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
普迈德（北京）科技有限公司 P	ro-med （Beijing） Technology Co., Ltd.	新型冠状病毒检测试剂	COVID-19 and COVID-19 Mutant Strain (B.1.1.7 Strain)Antigen Rapid Detection Kit (Colloidal Gold) COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) Influenza A+B and COVID-19 Antigen Combo Rapid Detection Kit (Colloidal Gold) COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold) COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	91110114078587382R	欧盟CE



PART 2

全球认证

Global Certificates

全球认证
Global Certificates

欧盟CE | 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-S5692)
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-S5693)

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

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

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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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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.
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	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

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 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

德国 BfArM | Germany BfArM

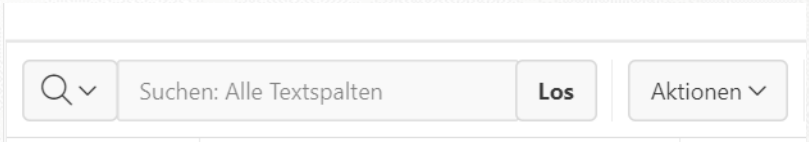
			Hersteller			Europäischer Bevollmächtigter					Sensitivität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche... Vertreiber	Testo...	%	95%iges Vertraue... intervall
AT864/21	COVID-19 Antigen-Schnellnachweis-Kit (Kolloidales Gold)	Nein	Pro-med (Beijing) Technology Co., Ltd.	Beijing	CN	Lotus NL B. V.	Hague	NL	Det...	POC (ohne Gerät)	94,74	89,53 - 97,43
AT863/21	COVID-19 Antigen-Schnellnachweis-Kit (Kolloidales Gold)	Ja	Pro-med (Beijing) Technology Co., Ltd.	Beijing	CN	Lotus NL B. V.	Hague	NL	Det...	POC (ohne Gerät)	93,98	88,58 - 96,92

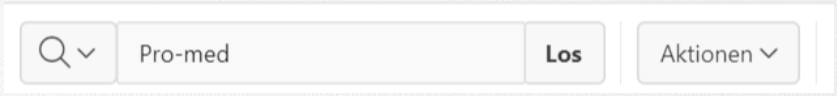
全球认证
Global Certificates

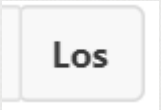
德国 BfArM | Germany BfArM

https://antigentest.bfarm.de/ords/f?p=110:100:2384549932382:::::

Pro-med technology 普迈德

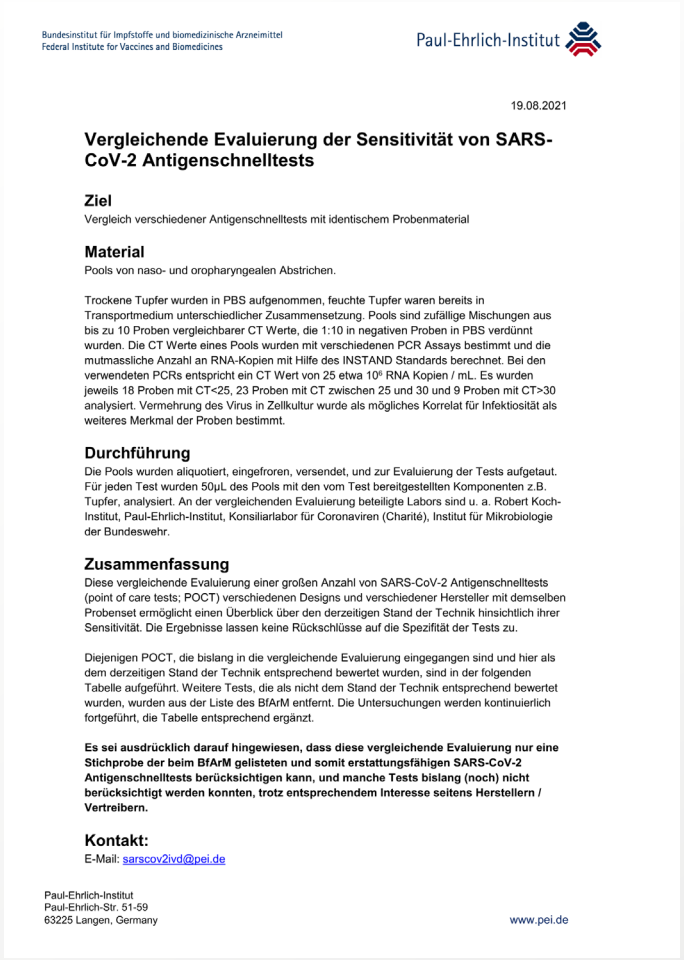






全球认证
Global Certificates

PEI



Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

19.08.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

Ziel
Vergleich verschiedener Antigenschnelltests mit identischem Probenmaterial

Material
Pools von naso- und oropharyngealen Abstrichen.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer CT Werte, die 1:10 in negativen Proben in PBS verdünnt wurden. Die CT Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmassliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein CT Wert von 25 etwa 10^6 RNA Kopien / mL. Es wurden jeweils 18 Proben mit CT<25, 23 Proben mit CT zwischen 25 und 30 und 9 Proben mit CT>30 analysiert. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Durchführung
Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50µL des Pools mit den vom Test bereitgestellten Komponenten z.B. Tupfer, analysiert. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung
Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit demselben Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

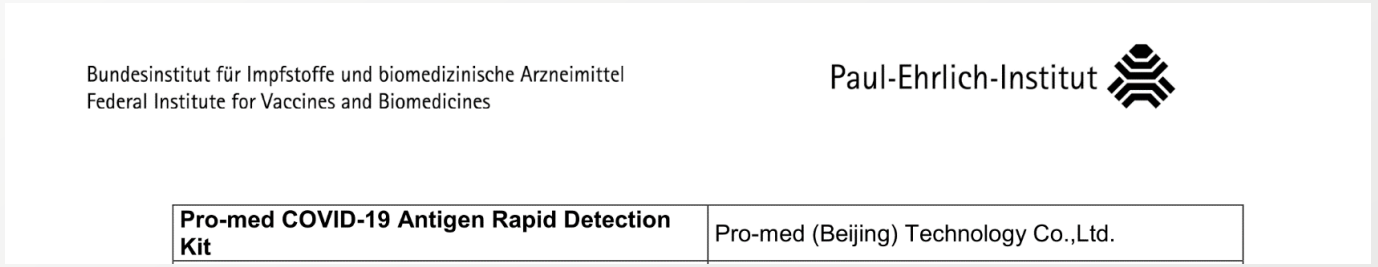
Diejenigen POCT, die bislang in die vergleichende Evaluierung eingegangen sind und hier als dem derzeitigen Stand der Technik entsprechend bewertet wurden, sind in der folgenden Tabelle aufgeführt. Weitere Tests, die als nicht dem Stand der Technik entsprechend bewertet wurden, wurden aus der Liste des BfArM entfernt. Die Untersuchungen werden kontinuierlich fortgeführt, die Tabelle entsprechend ergänzt.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:
E-Mail: sarscov2ivd@pei.de

Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen, Germany

www.pei.de



Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Pro-med COVID-19 Antigen Rapid Detection Kit	Pro-med (Beijing) Technology Co.,Ltd.

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PEI

https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=49

Pro-med technology 普迈德

Pro-med COVID-19 Antigen Rapid Detection Kit

Seite 6/6

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Elenco dispositivi individuati

Dati aggiornati al:16/05/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2105362	S	10 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105364	S	20 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105365	S	25 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105366	S	30 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105367	S	40 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105357	S	5 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105368	S	50 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105355	S	ONE TEST/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL
Dispositivo	2105349	S	One test/package	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL

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http://www.salute.gov.it/interrogazioneDispositivi/RicercaDispositiviServlet?action=ACTION_MASCHERA

Pro-med technology 普迈德

Denominazione:

Elenco dispositivi individuati

Dati aggiornati al:16/05/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2105362	S	10 TESTS/KIT	COVID-19 ANTIGEN RAPID DETECTION KIT(COLLOIDAL GOLD)	W0105090099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	13/05/2021		FABBRICANTE	PRO-MED (BEIJING) TECHNOLOGY CO., LTD.			CN
									MANDATARIO	LOTUS NL B.V.		822206675B01	NL

Denominazione: PRO-MED (BEIJING) TECH

Ricerca

Caution: type ‘PRO-MED (BEIJING) TECHNOLOGY CO., LTD.’ with English in Capitals

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奥地利自测版 | Austrian BASG

			Wuxi, Jiangsu, CN 214174.	
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Nasal swab	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Saliva sample	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam

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https://www.basg.gv.at/fuer-unternehmen/medizinprodukte/covid-19

Pro-med technology 普迈德

COVID-19 Tests

Selbstverpflichtung bezüglich Inverkehrbringen von SARS-CoV-2 Schnelltests NEU

Medizinprodukt, dem Hersteller und ggf. dem Bevollmächtigten. Die Liste wird regelmäßig aktualisiert.

- Selbstverpflichtung Inverkehrbringer SARS-CoV-2 Schnelltests (Stand: 18.05.2021)

Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Nasal swab	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold) - Saliva sample	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
Pro-med (Beijing) Technology Co., Ltd.	C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	Pro-med (Beijing) Technology Co., Ltd. C-3F, 8#, 738 Changliu Road, Machikou Town, Changping, 102202, Beijing, China	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam

Übersicht_Selbstverpflichtung_Inverkehrbringen_SARS-CoV-2_S... 1 / 70 85%

Selbstverpflichtung bezüglich Inverkehrbringen von SARS-CoV-2 Schnelltests

Inverkehrbringer		Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten	E-Mail
Firma	Anschrift				

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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

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

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

自由销售证书
CERTIFICATE OF FREE SALE

2021YB1835

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.

销往国家：斯里兰卡
Export to: Sri Lanka

买家：
Buyer: Evan Perera, CEO of Eva Corp (Private) Limited
地址：
Address: 3/3 Rockwood Place, Colombo 00700, Sri Lanka.

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。
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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 08 月 24 日
DATE OF ISSUE: August 24, 2021

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法国 | French Pro.

Dear Sir/Madam

We acknowledge receipt of the EC certification and the documents provided for your antigen test for professional use for nasal swabs.
The information provided is in accordance with national requirements. We will forward this information to the Ministry.

Kindly note that rapid antigen diagnostic tests on nasal swabs are subject to very restricted conditions of use, which must be organized by a regional health agency or an educational institution, and have not yet been deployed as part of the national strategy. As a result, and in order to avoid misuses or unregulated and unauthorized uses, the list of these products is not published on the ministerial platform.

Persons interested in the methods of marketing and use of these tests are invited to refer to the provisions of the amended Order of June 1, 2021 prescribing the general measures necessary for the management of the end of the health crisis.

Best regards,

Madame, Monsieur,

Welcome to contact us