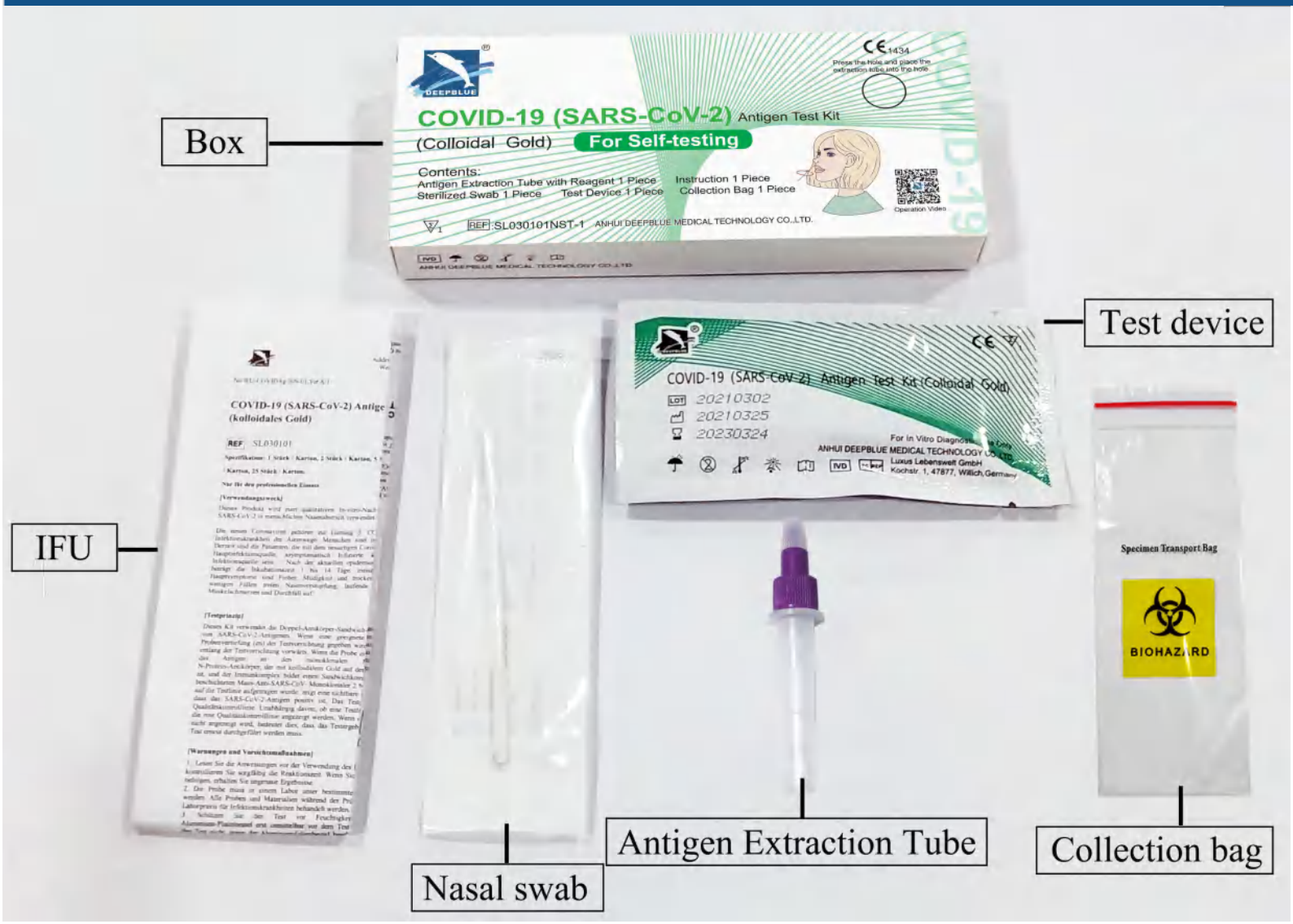
CE 1434

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

Self Testing

Anhui Deepblue Medical Technology Co.,Ltd.
Website: www.dbluemedical.com
Address: 4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei, Anhui, China.



Your kit contains the following materials

- Box
- IFU
- Nasal swab
- Test device
- Collection bag
- Antigen Extraction Tube

CERTIFICATE

EC Certificate No. 1434-IVDD-445/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anhui Deepblue Medical Technology Co., Ltd.

4th Floor,D-1#Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, China

in vitro diagnostic medical devices
for self-testing

COVID-19 (SARS-COV-2) Antigen Test Kit (Colloidal Gold)

SL030101NST-1,SL030101NST-2, SL030101NST-3, SL030101NST-5, SL030101NST-6, SL030101NST-7, SL030101NST-8, SL030101NST-9, SL030101NST-10, SL030101NST-11, SL030101NST-12, SL030101NST-15, SL030101NST-16, SL030101NST-17, SL030101NST-18, SL030101NST-19, SL030101NST-20, SL030101NST-25

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 22.07.2021

CE 1434

Issued under the Contract No. MD-96/2021
Application No: 183a/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Vice-President

DECLARATION OF CONFORMITY

MANUFACTURER:	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD. 4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone , 230088 Hefei, Anhui, People's Republic of China
EUROPEAN REPRESENTATIVE:	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany
PRODUCT:	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)
Models:	SEE ATTACHMENT
REF:	SEE ATTACHMENT
CLASSIFICATION:	SELF-TESTING
EDMA CODE:	15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III Article 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	EN ISO 13485:2016 EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO 14971:2012.
NOTIFIED BODY:	Polish Center for Testing and Certification 469 Puławska Street, 02-844 Warsaw，Poland
(EN) CERTIFICATE(S):	2021-07-22
START OF CE-MARKING:	2021-07-22
PLACE, DATE OF ISSUE:	HEFEI, 2021-07-28

SIGNATURE: chenfengling

CHEN FENGLING

GENERAL MANAGER

CE 1434

EC Declaration of Conformity

DOC-COVID-19 Ag(M/1)

DECLARATION OF CONFORMITY
ATTACHMENT

Specification	REF
1 piece per box	SL030101NST-1
2 pieces per box	SL030101NST-2
3 pieces per box	SL030101NST-3
5 pieces per box	SL030101NST-5
6 pieces per box	SL030101NST-6
7 pieces per box	SL030101NST-7
8 pieces per box	SL030101NST-8
9 pieces per box	SL030101NST-9
10 pieces per box	SL030101NST-10
11 pieces per box	SL030101NST-11
12 pieces per box	SL030101NST-12
15 pieces per box	SL030101NST-15
16 pieces per box	SL030101NST-16
17 pieces per box	SL030101NST-17
18 pieces per box	SL030101NST-18
19 pieces per box	SL030101NST-19
20 pieces per box	SL030101NST-20
25 pieces per box	SL030101NST-25

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

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

TÜV SÜD Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
4th Floor, D-1# Zone
Pearl Industrial Park
106 Innovation Avenue, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis(Polyamines) and Cell Preservation Solution**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01

Report No.: SH21130301

Valid from: 2021-06-22
Valid until: 2024-06-21

Date, 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Applied Standard(s):

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

Facility(ies):

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Nasal Swab

Manufactured by Anhui Deep Blue Medical Technology Co., Ltd, China - www.dbluemedical.com/

Device identification number
1815

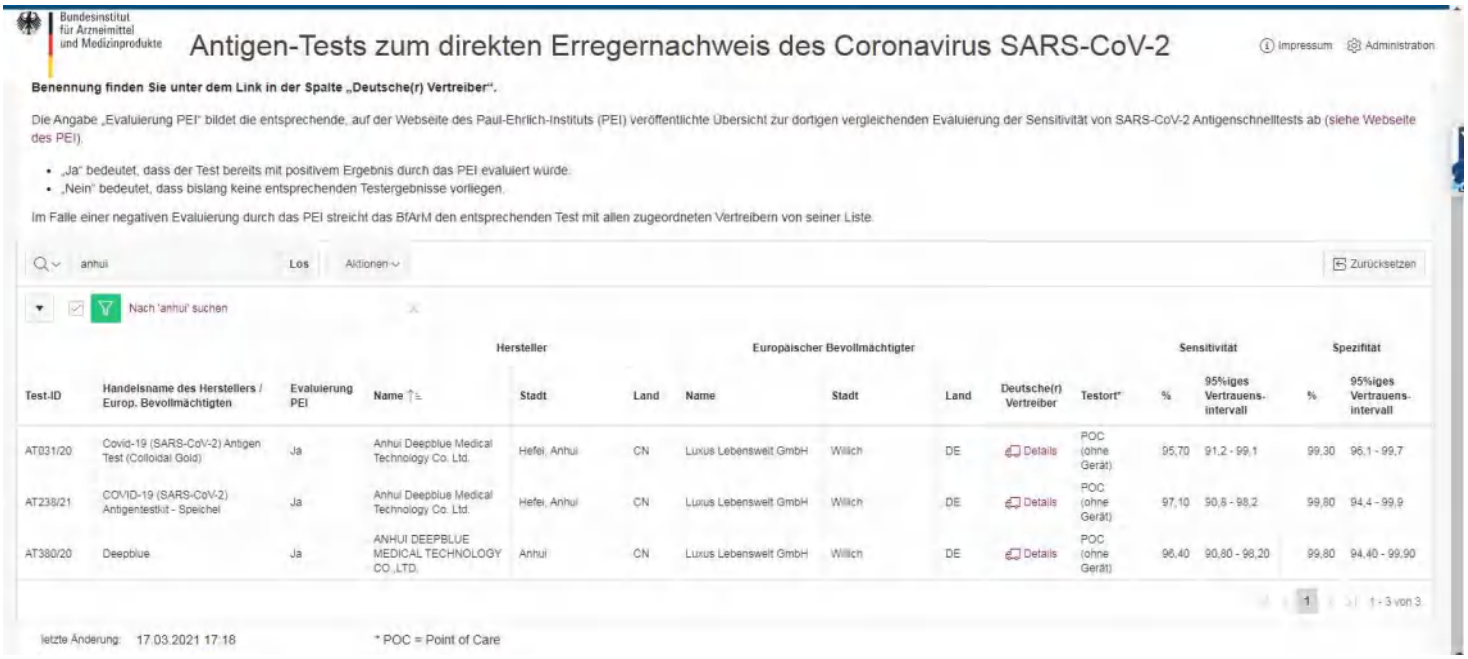
CE Marking	✓ Yes
HSC common list	✓ Yes
HSC mutual recognition	✓ Yes
Format	Near POC / POC
Physical Support	Lateral flow
Target	Antigen

Specimen	Anterior nasal swab, Nasal swab
Commercial Status	Commercialised
Last Update	2021-07-07 05:18:58 CET

Comments

Please check attached UK national systematic evaluation report with the detailed data from UK government validation, performed by University of Oxford. Public Health England Porton Down. 132 brands were tested and only 4 suppliers have passed all of the Phase 3B validation, including ANHUI DEEPBLUE MEDICAL. The link of this report: https://www.medrxiv.org/content/10.1101/2021.01.13.21249563v1.full-text Please check attached UK national systematic evaluation report with the detailed data from UK government validation, performed by University of Oxford. Public Health England Porton Down. 132 brands were tested and only 4 suppliers have passed all of the Phase 3B validation, including ANHUI DEEPBLUE MEDICAL. The link of this report: https://www.medrxiv.org/content/10.1101/2021.01.13.21249563v1.full-text And we have attached the MHRA registration certificate. Also the registration in Germany, registration in Italy, registration in Portugal and so on.

Show HSC list status history



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

anhui Los Aktionen Zurücksetzen

Nach 'anhui' suchen

	Hersteller				Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche(r) Vertreiber	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall
AT031/20	Covid-19 (SARS-CoV-2) Antigen Test (Colloidal Gold)	Ja	Anhui Deepblue Medical Technology Co. Ltd.	Hefei, Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	95,70	91,2 - 99,1	99,30	96,1 - 99,7
AT238/21	COVID-19 (SARS-CoV-2) Antigentestkit - Speichel	Ja	Anhui Deepblue Medical Technology Co. Ltd.	Hefei, Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	97,10	90,8 - 98,2	99,80	94,4 - 99,9
AT380/20	Deepblue	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	96,40	90,80 - 98,20	99,80	94,40 - 99,90

1 1 - 3 von 3

letzte Änderung: 17.03.2021 17:18

* POC = Point of Care

BfArM List with PEI Validation

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

安徽深蓝医疗科技股份有限公司 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
安徽深蓝医疗科技股份有限公司	Anhui Deepblue Medical Technology Co., Ltd.	新型冠状病毒检测试剂	COVID-19(SARS-CoV-2) Antibody Test Kit(Colloidal Gold) COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) COVID-19 (SARS-CoV-2) Antibody & Antigen Combo Test Kit (Colloidal Gold)	913401005501903714	欧盟CE

友情链接

DeepBlue White List

COVID-19 (SARS-CoV-2) Antigen test kit

(Self-Testing)

Specification	1 pcs/box 5 pcs/box 25 pcs/box
Specimen	Human Anterior Nasal Swab
Storage	4~30℃

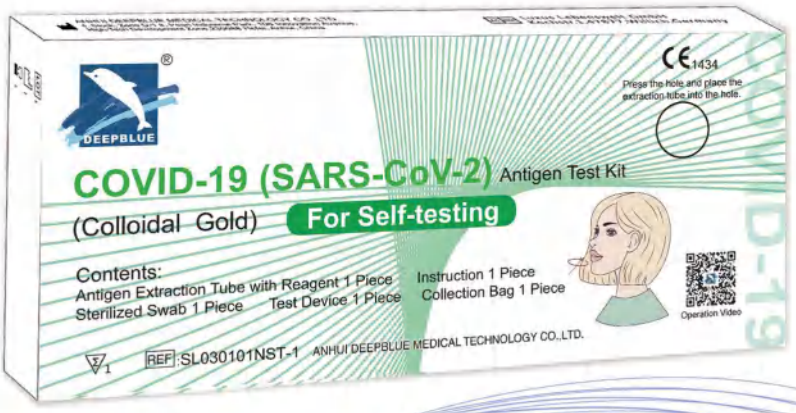
PERFORMANCE

SENSITIVITY: 96.4%(95%CI: 90.8%-98.2%)

SPECIFICITY: 99.8%(95%CI: 94.4%-99.9%)

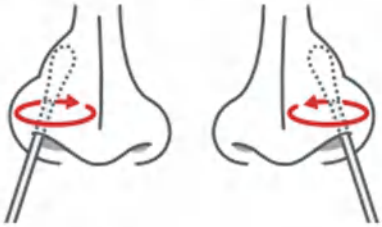
PRODUCT FEATURES

- Room temperature storage.
- No need instrument, get results within 15 minutes.
- Identify acute or early infection.
- No reduction in sensitivity test against the UK, South African, Brazilian and Delta variant.

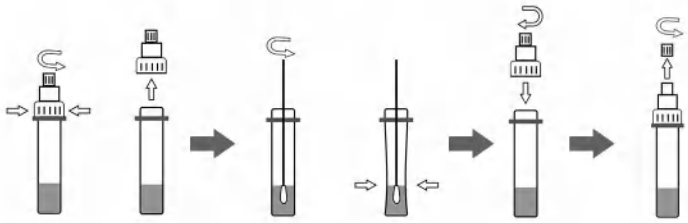


TEST PROCEDURE

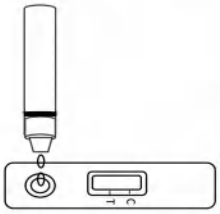
1.Specimen Collection



2.Specimen Preparation



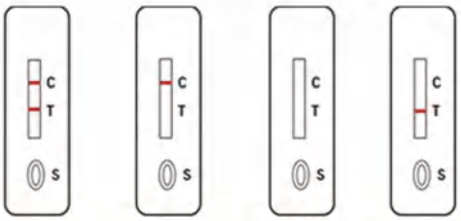
3.Testing



Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer. Interpret the results at 15 minutes, and the results after 30 minutes are no longer valid.

4.Interpretation of test results

15 minutes



Positive Negative Invalid Invalid

Scan the following QR code to watch the demonstration video on YouTube.

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

【Address】4th, Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei 230088, Anhui, China

【Website】www.dbluemedical.com 【Contact】0551-65326797

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00164917

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **26.07.2021**		Registriernummer / Registration number **DE/CA20/01-IVD-Luxuslebenswelt-38/21**
	Rechtsgrundlage / legal basis ☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)		
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)

	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.**		
	Staat / State **CN**		
	Ort / City **Hefei**		Postleitzahl / Postal code **230088**
	Straße, Haus-Nr. / Street, house no. **4th Floor, D-1# Zone, Pearl Industrial Park,106 Innovation Avenue, High-Tech Development Zone**		
	Telefon / Phone **0086-551-65326797**		Telefax / Fax **0086-551-65326758**
	E-Mail / E-mail **284423655@qq.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Lin Sun**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification ☐ Produkt der Liste A, Anhang II / Device of List A, Annex II ☐ Produkt der Liste B, Anhang II / Device of List B, Annex II ☒ Produkt zur Eigenanwendung / Device for self-testing ☐ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG ☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)**
	Produktbezeichnung / Name of device **COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)**
	Angabe der benutzten Nomenklatur / Nomenclature used ☒ EDMS-Klassifikation / EDMS Classification ☐ GMDN
	Nomenklaturcode / Nomenclature code **15-70-90-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
	Kurzbeschreibung / Short description In Deutsch / In German **Dieses Produkt wird für den qualitativen In-vitro-Nachweis des SARS-CoV-2-Antigens in menschlichen Nasenabstrichproben verwendet. Es ist für den persönlichen Gebrauch durch ungeschulte Laien als Schnelltestmethode für eine neuartige Coronavirus-Infektion bestimmt. Bitte treffen Sie jedoch keine medizinische Entscheidung ohne Rücksprache mit dem Arzt.** **Es ist für Benutzer ab 15 Jahren geeignet. Benutzer unter 15 Jahren sollten mit Hilfe von Erwachsenen getestet werden. Sowohl symptomatische als auch asymptomatische Infektionen können getestet werden.**
	In Englisch / In English **This product is used for in vitro qualitative detection of the SARS-CoV-2 antigen in human nasal swab specimen. It is intended for personal use by untrained layman as a rapid test method for novel coronavirus infection. However, please do not make a medical decision without consulting with the doctor.** **It is suitable for users over 15 years old. Users under 15 years of age should be tested with assistance of adults. Both symptomatic and asymptomatic infections can be tested.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s) **1434/1434-IVDD-443/2021**
	☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation **Performanceevaluation.pdf**

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Willich**

Datum
Date **2021-07-22**

Name **Lin Sun**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Nadine Schlingmeier**		Telefon / Phone **0211-475-3853**