CERTIFICATE

EC Certificate No. 1434-IVDD-483/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Goldsite Diagnostics Inc.
No. 103C, 503C & 504D, Technology Building & No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-District, Nanshan District, Shenzhen, China

in vitro diagnostic medical devices
self-testing

SARS-CoV-2 Antigen Kit (Colloidal Gold)

REF: CG123001, CG123003, CG123005, CG123007, CG123025

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 10.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 10.11.2021

CE 1434

Issued under the Contract No. **MD-40/2021**
Application No: **397/2020**
Certificate bears the qualified signature.
Warsaw, 10/11/2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:14:07 +01'00'

Vice-President
Mgr. Anna Wyroba

GOLDSITE DIAGNOSTICS INC.
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Shenzhen, China, 518067
Email: export@goldsite.com.cn
Website: www.goldsite.com.cn

Other 3rd party certificates and recommendations

EU common list

https://covid-19-diagnostics.jrc.ec.europa.eu/devices/detail/1197

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests;
A common standardised set of data to be included in COVID-19 test result certificates; and
A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Goldsite Diagnostic Inc.	SARS-CoV-2 Antigen Kit (Colloidal Gold)	1197	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	93.04% sensitivity; 100% specificity Nasal swab	BE, BG, CY, FR, RO, SI, ES	UK	FR, DE[2], ES UK	*Unknown*	14 July 2021

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COVID-19 In Vitro Diagnostic Medical Device - detail

SARS-CoV-2 Antigen Kit (Colloidal Gold)

Manufactured by Goldsite Diagnostics Inc, China - en.goldsite.com.cn/

Device identification number	1197
CE Marking	Yes
HSC common list	Yes
HSC mutual recognition	Yes
Format	Near POC / POC
Target	Antigen
Specimen	Nasal swab, Other
Commercial Status	Commercialised
Last Update	2021-07-13 06:05:32 CET
Comments	

Hide HSC list status history

View current HSC list

2021-07-13 Added to mutual recognition list

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Website: www.goldsite.com.cn

Germany BfArM recommendation list
https://antigentest.bfarm.de/ords/f?p=110:100:5818155552924:::::&tz=8:00

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Cc

Impressum Administration

potentieller Vertreiber eines entsprechenden Antigenschnelltests gibt.

Änderungen zu bestehenden Listungen oder Neuanträge zur Aufnahme in die Marktübersicht können nur vom Hersteller des Tests, seinem europäischen Bevollmächtigten oder einem vom Hersteller schriftlich beauftragten Verfahrensbevollmächtigten beantragt werden.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Eine Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** finden Sie unter diesem Link.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

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 CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

Goldsite | Los | Aktionen | Zurücksetzen

Nach 'Goldsite' suchen

			Hersteller			Europäischer Bevollmächtigter		
Test-ID	Handelsname	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	La
AT533/21	SARS-CoV-2 Antigen Kit (Colloidal Gold)	Ja	Goldsite Diagnostics Inc.	Shenzhen	CN	CMC MEDICAL DEVICES & DRUGS, S.L.	Málaga	ES

1 - 1 von 1

letzte 22.11.2021 09:34 * POC = Point of Care

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Germany Paul-Ehrlich-Institut Evaluation

https://www.pei.de/EN/newsroom/dossier/coronavirus/test-systems.html

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

Paul-Ehrlich-Institut

25.06.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)	Goldsite Diagnostics Inc.

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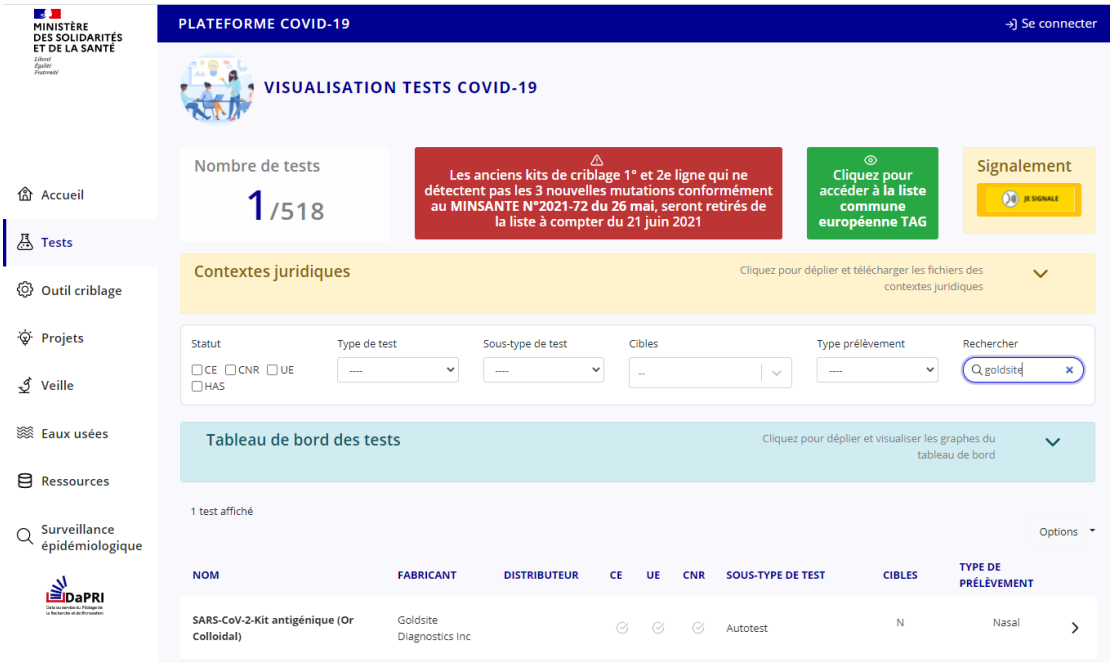
Website: www.goldsite.com.cn

France ANSM self-test special approval

https://covid-19.sante.gouv.fr/tests



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UK DHSC Phase 3A validation

https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices

Department of Health & Social Care

Guidance

Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices)

Updated 11 October 2021

Table 1: summary of lateral flow devices that have passed phase 3a validation

Lateral flow device	Status	Date evaluation completed
Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold)	Pass	8 July 2021

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Malaysia recommendation list

https://portal.mda.gov.my/announcement/596-list-of-recommended-for-use-of-covid-19-ivd-test-kit.html

List of Recommended for Use of Covid-19 IVD Test kit (Professional use only)

SPECIAL ACCESS LIST OF COVID-19 TEST KIT (FOR PROFESSIONAL USE ONLY)

The list of Covid-19 Antibody, Antigen and Nucleic Acid Amplification Test (NAAT) that is recommended for use based on the decision on the consensus of the Covid-19 Test Kit Expert committee is as follows.

All test submissions are scored according to: -

- the manufacturer reported clinical and analytical performance
- the evaluation test results from testing facilities are according to the committee evaluation criteria set by Clinical expert
- Supporting Documents for COVID-19 IVD Test Kits **Special Access**

Below is the list of all tests that have been selected to date and the status is Recommended for Use (please note: list is updated on a routine basis).

Notes:

***Sample type and lot number is based on testing facility evaluation report.**

114	Viga Gemilang Enterprise	Goldsite SARS-CoV-2 Antigen Kit	Goldsite Diagnostic Inc. China.	CG123025	20210415	RTK Antigen	Nasal Swab

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DECLARATION OF CONFORMITY

Manufacturer	Goldsite Diagnostics Inc.
Address	No.103C, 503C & 504D, Technology Building & No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-District, Nanshan District, Shenzhen, China, 518067
European Representative	CMC MEDICAL DEVICES & DRUGS, S.L. C/ Horacio Lengo No 18, CP 29006, Málaga-Spain
Product Information	SARS-CoV-2 Antigen Kit (Colloidal Gold) (for self-testing)
GMDN terms	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), self-testing. GMDN Code: 65454
Conformity Assessment Route: Annex Ⅲ ,point 6	*We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.*
General Applicable Directives:	*In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Of 27 October 1998* *Classification: Device for self-testing* *Directive 98/79/EC, Article 9, Annex Ⅲ*
Standards Applied	EN ISO 13485:2016 BS EN 13612:2002 ISO 14971:2019 EN ISO 23640:2015 ISO 15223-1:2016 EN ISO 18113-1: 2011 EN ISO 18113-4: 2011 EN 62366-1: 2015

CE 1434

Place, date of issue: Shenzhen, P.R. China, November 10, 2021

Signature of General Director

SIGNATURE

STAMP