GOLDSITE DIAGNOSTICS INC.
No. 103C, 503C & 504D, Technology Building &
No. 3A & 4A, Technology Building Annex,
Zhaoshang Sub-District, Nanshan District,
Shenzhen, China, 518067
Email: export@goldsite.com.cn
Website: www.goldsite.com.cn

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.

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

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