



# CERTIFICATE

---

**EC Certificate No. 1434-IVDD-524/2021**

**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)**

*The list of versions of medical devices covered by this certificate is provided in the annex 1.*

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 29.12.2021 to 27.05.2025

The date of issue of the Certificate: 29.12.2021

The date of the first issue of the Certificate: 10.11.2021



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

**President**



## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-524/2021**

*List of medical devices covered by the certificate:*

REF Numbers
CG123001, CG123003, CG123005, CG123007, CG123025, CG123201



Issued under the Contract No. MD-40/2021  
Application No: 397/2020  
Certificate bears the qualified signature.  
Warsaw, date next to signature

**President**