



## 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)  
REF: CG123001, CG123003, CG123005, CG123007, CG123025

**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    ISO 15223-1:2016  
BS EN 13612:2002    EN ISO 18113-1: 2011  
ISO 14971:2019    EN ISO 18113-4: 2011  
EN ISO 23640:2015    EN 62366-1: 2015



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

**Signature of General Director**

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