



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	<i>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.</i>	
General Applicable Directives:	<i>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</i>	
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

SIGNATURE



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