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)
Conformity Assessment Route: Annex Ⅲ	*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: Non listed device in directive 98/79/EC* *Directive 98/79/EC, article 9, annex* Ⅲ
Standards Applied	EN 980:2008 EN 13612:2002 EN ISO 14971:2000 EN 375:2001 EN591

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Place, date of issue: Shenzhen, P.R. China, September 25, 2020

Signature of General Director

SIGNATURE

GOLDSITE DIAGNOSTICS INC 深圳市国赛生物技术有限公司

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