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 & Influenza A/B & RSV 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: Neither listed in Annex Ⅱ, IVDD 98/79/EC, nor self-testing device.* *Directive 98/79/EC, Article 9, Annex Ⅲ*
Standards Applied	EN ISO 13485:2016 BS EN 13612:2002, ISO 14971:2019. ISO 15223-1:2016 EN ISO 18113-1: 2011 EN ISO 18113-2: 2011

Place, date of issue: Shenzhen, P.R. China, May 23, 2022

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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