EC Declaration of Conformity

Manufacturer:	Xiamen AmonMed Biotechnology Co.,Ltd.
Address:	Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian, China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24,1076DE Amsterdam, Netherlands
Product Name:	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Product specification and Reference No	For use with saliva specimen: 1 test/kit: CG01Ag-01S-ST 5 tests/kit: CG01Ag-05S-ST 25 tests/kit: CG01Ag-25S-ST
Classification:	Self-test IVD
Conformity-Assessment Procedure:	Directive *(98/79/EC)*on In Vitro Diagnostic Medical Device, Annex III section 6

We herewith declare that the above mentioned products meet the provisions of In Vitro Diagnostic Directive (98/79/EC). All supporting documentation is retained under the premises of the manufacturer. We have sole responsibility for issuing the Declaration of Conformity.

Applied standards:

EN ISO 13485:2016
EN ISO 14971:2019
ISO/TR 24971-2020
EN 62366:2015
MDCG 2021-21
EN ISO 18113-4:2011
EN ISO 18113-1:2011
EN ISO 17511:2003
EN 13532:2002
EN ISO 23640:2015
EN ISO 15223-1:2016
EN 13612:2002
EN 13641:2002

Notified Body:	Polish Center for Testing and Certification, 469 Puławska Street, 02-844 Warsaw Identification number: 1434 CE certificate No. 1434-IVDD-467/2021
Signature:	
Name and Position:	Fenfang Xie/Management Representative
First Issue Date:	2021.10.15
Issue Date:	2021.10.15