



EC Declaration of Conformity



Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name: Xiamen AmonMed Biotechnology Co.,Ltd.

Address: Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian, China.

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Product Name	Type
COVID-19 IgM/IgG test kit (Colloidal Gold)	25 tests/kit,50 tests/kit
COVID-19/Influenza A virus/Influenza B virus test kit (Rare earth nano fluorescence immunochromatography)	25 tests/kit,50tests/kit

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 14971:2012

EN 15223-1:2016

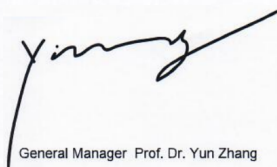
EN ISO 18113-1:2011

EN ISO 18113-3:2011

EN ISO 13485:2016

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Signature:


General Manager Prof. Dr. Yun Zhang




Authorized Signature (S)

Date: March 9th,2020

