Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Sansure Biotech Inc.
No. 680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province
PEOPLE'S REPUBLIC OF CHINA

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

Please refer to Annex to this Declaration

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 13485:2016 & EN ISO 13485:2016**
- **ISO 9001:2015**

Corporate Contact Information

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Annex A – List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	S3109E	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	Coronavirus	The SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method) is an in vitro diagnostic test for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal or nasal swab specimens, which will provide information for clinical doctors to prescribe correct handing. Components of the Diagnostic Kit: SARS-CoV-2-Antigen Test Cassette (individually in a foil pouch with desiccant) Lysis Buffer Nozzle Cap with Protective Cover	15.04.80.19	**Others**
2	S3110E	SARS-CoV-2 Rapid Antigen Test (Colloidal Immunization Method)	Coronavirus	The SARS-CoV-2 Rapid Antigen Test (Colloidal Immunization Method) is an in vitro diagnostic test for the qualitative detection of novel coronavirus in Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. It will provide information for clinical doctors to prescribe correct handing. Components of the Diagnostic Kit: SARS-CoV-2-Antigen Test Cassette (individually in a foil pouch with desiccant) SARS-CoV-2-Buffer Extraction Tube Nozzle with Filter	15.04.80.19	**Others**
3	S3111E	SARS-CoV-2 Antigen Sealing Tubular Test (Colloidal Gold)	Coronavirus	SARS-CoV-2 Antigen Sealing Tubular Test (Colloidal Gold) is used to qualitatively detect the antigen of SARS-CoV-2 in human nasal swabs samples in vitro. This product is only for medical institutions and professionals. Components of the Diagnostic Kit: 1. SARS-CoV-2-Antigen Test Tube (individually in a foil pouch with desiccant) 2.SARS-CoV-2-Diluent	15.04.80.19	**Others**

4	S3108E	Human Papillomavirus DNA (23 genotypes) Diagnostic Kit (PCR-Fluorescence Probing)	Other HPV - NA Reagents	Human Papillomavirus DNA (23 genotypes) Diagnostic Kit (PCR-Fluorescence Probing) is used for in vitro qualitative detection of human papillomavirus (type 6, 11, 16, 18, 26, 31, 33, 35, 39, 42, 43, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 81, 82) presented in exfoliated cells from females' cervix. Components of the Diagnostic Kit: HPV Genotype-Enzyme Mix HPV(16/18/33/39)-PCR Mix HPV(45/59/35/66)-PCR Mix HPV(51/52/53/68)-PCR Mix HPV(31/56/58/β-globin)-PCR Mix HPV(6/26/81/82)-PCR Mix HPV(11/42/43/73)-PCR Mix HPV Genotype-Negative Control HPV Genotype-Positive Control	15.04.08.43	**Others**