# Declaration of Conformity

**MANUFACTURER**

- GenSure Biotech Inc.,
- Address: B1-78, Rizhongtian Science and Technology Park, No.585 Tianshan Street, Shijiazhuang High-tech Zone, 050000, Hebei, P.R.China.
- Tel: 0086-311-89937995
- Fax: 0086-311-89937997

**MANUFACTURER SITE**

- Address: 3/F, Block 1, Boyun Building, No. 9 Fengchan Rd, Economic-Tech Development Zone, Shijiazhuang, 050000, Hebei, P.R China.

**EC-REPRESENTATIVE**

- QualRep Services B.V.
- Address: Utrechtseweg 310 - Bldg B42, NL-6812 AR Arnhem, The Netherlands
- E-mail: globalreg@qservegroup.com

**PRODUCT**

- Name: GenSure$^{TM}$ COVID-19 Antigen Rapid Test Kit
- Commercial Name: GenSure$^{TM}$ COVID-19 Antigen Rapid Test Kit
- Generic device term: Detection Card for COVID-19
- Short description and intended use: This product is used for the qualitative testing of novel coronavirus antigen in human nasal/throat swabs. Detection of SARS-CoV-2 antigen has the advantages of high sensitivity, early diagnosis, and the ability to determine whether the suspect is infected.
- Classification: Other
- GMDN Code: 64787

**CLASSIFICATION**

- Others

(IVD Device other than the ones listed in Annex II -IVDD 98/79 as List A , List B and Self testing)

**CONFORMITY ASSESSMENT**

Self-declaration of Conformity

**ROUTE**

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. This declaration is based on conformity to Annex III (excluding Annex III.6). All supporting documentation is retained under the premises of the manufacturer and can be

available through EU representative.

STANDARDS APPLIED:

- ISO 13485: 2016 Medical devices
- EN ISO 18113-2: 2013 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use
- EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements
- EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971: 2012 Medical devices. Application of risk management to medical devices
- EN ISO 17511: 2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

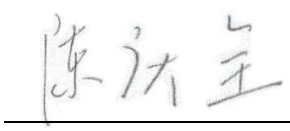
START OF CE-MARKING: 2020-05-20
PLACE, DATE OR ISSUE: Shijiazhuang, 2020-06-30

**Rigistration Information:**

**As stipulated and demanded by the aforementioned directive，the European Databank on Medical Device （EUDAMED）is established as of May.1,2011, the Netherlands competent authority is notified of the manufacturer's GenSure Biotech Inc., IVD medical device and has allocated registration numbers shown :**

**as of today and without any further notice from the respective Competent Authorities, GenSure can be considered as the respective devices as officially notified.**

SIGNATURE:



Name Print: Qingquan Chen
Position: Manufacture Representative
Date: 2020-06-30