EC Declaration of Conformity

Name and address of the manufacturer:	GenSure Biotech Inc., 3/F, Block 1, Boyun Building, No. 9 Fengchan Rd, Economic-Tech Development Zone, Shijiazhuang, 050000, Hebei, P.R China.

We declare under our sole responsibility that

the medical device:	**COVID-19 IgM Rapid Test** **COVID-19 IgG/IgM Rapid Test**
of class:	**Other**

according to aticle 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:	**Directive 98/79/EC Annex III**
Name and address of the Authorised Representative	QualRep Services B.V. Utrechtseweg 310 - Bldg B42, NL-6812 AR Arnhem, The Netherlands

CE

Shijiazhuang, Mar.11.2020	Terry Chen Sales Director
Place, date	Name and function

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™ COVID-19 IgM Rapid Test
- Commercial Name: GenSure™ COVID-19 IgM Rapid Test
- Generic device term: Detection Card for COVID-19
- Short description and intended use : This product is used for the qualitative testing of new coronavirus SRAS-CoV-2 IgM antibodies in human serum, plasma or whole blood. Detection of SRAS-CoV-2 IgM antibody has the advantages of high sensitivity, early diagnosis, and the ability to determine whether the suspect is infected.
- GMDN code: No GMDN code yet
- Classification: Other

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 (labelling) - Part 2: In vitro diagnostic reagents for professional use
- EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling 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: 2015 Fire resistance tests for non-loadbearing elements - Walls
- 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
- EN ISO 11607-1:2014 PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 1: REQUIREMENTS FOR MATERIALS, STERILE BARRIER SYSTEMS AND PACKAGING SYSTEMS

START OF CE-MARKING: 2020-02-01
PLACE, DATE OR ISSUE: **Shijiazhuang,2020-03-11**

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: 2020-03-11