

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
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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

- OSMUNDA Medical Technology Service GmbH
- Address: Von Oppen-Weg 15, 14476 Potsdam, Germany
- E-mail: eu@osmundacn.com
- Fax: +49-30-2215-0446
- Tel: +49-30-5059-0627

PRODUCT

- Name: GenSure™ COVID-19 Antigen Rapid Test Kit
- Commercial Name: GenSure™ 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 swabs and saliva specimens. 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
- EDMS Code: 15.04.80.90.00

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

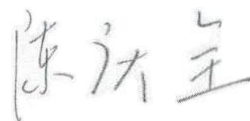
PLACE, DATE OR ISSUE: Shijiazhuang, 2020-06-30

Registration Information:

The manufacturer's GenSure Biotech Inc., IVD medical device has allocated registration numbers shown :

AT/CA01/I0018391-00

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



Name Print: Qingquan Chen

Position: Manufacture Representative

Date: 2020-06-30