PROVETTE CON BUFFER PRONTE ALL' USO

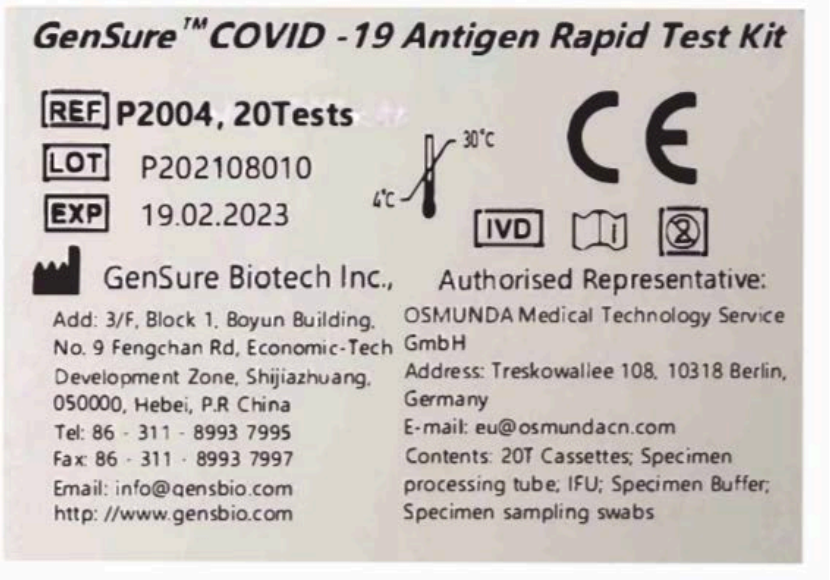
SCHEDA TECNICA – 2019-nCoV Antigen Test

CODICE	DESCRIZIONE	SERIE	CONFEZIONAMENTO
P2004	Test Antigenico Rapido Anti SARS-CoV-2	COV19	20 PZ/CONF.

STANDARD E CONFORMITA'	EN ISO 13485:2016 DIRETTIVA EUROPEA 98/79/EC ALLEGATO III
CLASSE DISPOSITIVO REPERTORIO	IVD RDM: 2179622 CND: W0105099099
PRINCIPIO - PERFORMANCE	GENSURE 2019-NCOV ANTIGEN TEST (FLUSSO LATERALE) È UN SAGGIO IMMUNOCROMATOGRAFICO PER L' IDENTIFICAZIONE RAPIDA DEL NUOVO CORONAVIRUS (2019-NCOV) DERIVANTE DA ANTIGENI ESTRATTI DA CAMPIONI PRELEVATI TRAMITE TAMPONI NASALI E NASOFARINGEI. TEMPO DI RILEVAMENTO 10/15 MINUTI. IL TEST E' DI FACILE ESECUZIONE E RICHIEDE POCHI PASSAGGI PER L' ESECUZIONE. DOTARSI DI DPI ADEGUATI PER LA SICUREZZA DELL' OPERATORE. NON SONO NECESSARIE MISURE DI CONTENIMENTO O PREVENZIONE QUALI, CAPPE BIOHAZARD. E POSSIBILE ANALIZZARE CAMPIONI CONSERVATI IN TERRENI DI TRASPORTO VIRALE IN GENERE. SOLO PER USO DIAGNOSTICO IN VITRO. SOLO PER USO PROFESSIONALE. I TAMPONI NASALI O NASOFARINGEI SONO CONFEZIONATI SINGOLARMENTE IN BLISTER DI CARTA CON APERTURA FACILITATA. LATEX FREE, FTALATO FREE, APIROGENO. ESENTI DA INTERFERENZE CON LA RICERCA DI DNA/RNA APPARTENETE AI PATOGENI RICERCATI SENSIBILITÀ:96,86%(93,29%~98,84%) SPECIFICITÀ:100%(98,97%~100%) TOTALE ACCORDATO: 98,91% (97,63%~99,60%)
PRODUTTORE	GENSURE BIOTECH INC.
INDIRIZZO	3/F, Block 1, Boyun Building, No. 9 Fengchan Road Shijiazhuang Economic-Technological development Zone, Hebei, P.R.China
REFERENTE EUROPEO	OSMUNDA MEDICAL TECHNOLOGY SERVICE GMBH Treskowallee 108, 10318 Berlin, Germany

CONSERVAZIONE CARTUCCIA REF. P2004

1. CONSERVARE A 2~30℃ IN LUOGO ASCIUTTO FINO ALLA SCADENZA RIPORTATA SULLA CONFEZIONE. NON CONGELARE.
2. IL TEST DEVE ESSERE USATO ENTRO 1H DA UQNADO VIENE RIMOSSO DALLA SUA CONFEZIONE.
3. TENERE LONTANO DAI RAGGI SOLARI E FONTI DI CALORE IN GENERE.
4. IL KIT È STABILE FINO ALLA DATA DI SCADENZA INDICATA SULLA CONFEZIONE



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

- OSMUNDA Medical Technology Service GmbH
- Address: Treskowallee 108, 10318 Berlin, Germany
- E-mail: eu@osmundacn.com
- Tel: +49-30-8186 5123
- Fax: +49 30 4699 5929

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 swab / 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

Rigistration 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.

SIGNATURE:

河北精硕生物科技有限公司
GENSURE BIOTECH INC.

TC Shijiazhuang

Name Print: Terry Chan
Position: Manufacture Representative
Date: 2020-08-31