FISA TEHNICA PRODUS

Denumire Produs: Test Rapid Saliva Encode
Producator: Zhuhai Encode Medical Engineering Co., Ltd

Descriere: Dispozitivul de testare rapida COVID-19 este un imunocromatografic destinat detectarii directe si calitative a antigenelor nucleocapsidei SARS-CoV-2 din proba de saliva de la persoane care sunt suspectate de COVID-19. Produs recunoscut de Comisia Europeana (vezi detaliile suplimetare de mai jos).

Testul este destinat uzului profesional (cadre medicale)

Specificitate = 100%
Sensibilitate = 93.86%
Acuratete: 97.14%

European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices > COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 In Vitro Diagnostic Medical Device - detail

SARS-COV-2 Antigen Rapid Test (Saliva)

Manufactured by Zhuhai Encode Medical Engineering Co., Ltd, China - http://www.encode.com.cn/

Device identification number	1616
CE Marking	Yes
HSC common list	No
HSC mutual recognition	No
Format	Near POC / POC
Physical Support	Cassette
Target	Antigen
Specimen	Saliva
Pathogens detected	SARS-CoV
Commercial Status	Commercialised
Last Update	2021-08-27 09:38:32 CET
Comments	We update the information of our product
Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	No
Method	Immunochromatography

CE EC Declaration of Conformity CE

Manufacturer:	Zhuhai Encode Medical Engineering Co., Ltd. Add:No.020,Honghui 2nd RD Hongqi Industrial Zone,Jinwan District,Zhuhai,P.R China(519090)
Whose Single Authorized EU-Representative:	CMC Medical Devices& Drugs S.L. Add:C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Name:	SARS-COV-2 Antigen Rapid Test Device(Saliva)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016,EN ISO 15223-1:2016,EN ISO 14971:2012, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:
Name: SUN Yifeng — Sun Yifeng
Title: General manager
Place/Date: Zhuhai.2021-04-08

EC Declaration of Conformity **No.YK-DoC-05,A/0**
Page 1/1

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106272 0001 Rev. 00

Holder of Certificate: **Zhuhai Encode Medical Engineering Co., Ltd**
NO. 020, Honghui 2nd Rd
Hongqi Industrial Zone, Jinwan District
519090 Zhuhai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of in Vitro Diagnostic Rapid Test for the Detection of Fertility, Drugs of Abuse, Cardiac Markers, Tumor Markers, Infectious Diseases, Sexually Transmitted Disease, including professional use, near patient and self testing, Microbiological Diagnostic Kit and related instruments, Immunofluorescence Analyzer and Immunofluorescence Reagents**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 106272 0001 Rev. 00

Report No.: GZ1942801

Valid from: 2021-05-11
Valid until: 2024-05-10

Date, 2021-05-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106272 0001 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Zhuhai Encode Medical Engineering Co., Ltd
NO. 020, Honghui 2nd Rd, Hongqi Industrial Zone, Jinwan District,
519090 Zhuhai, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2021/13042021.10

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Zhuhai Encode Medical Engineering Co., Ltd.
No.020,Honghui 2nd RD Hongqi Industrial Zone, Jinwan District, Zhuhai, P.R China(519090)

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC on in vitro diagnostics as amended.
From 26 May 2022, manufacturer must fully comply with the IVDR in order to be placed their products in the European market.

The products in Annex I was registered in Spanish MOH with number **RPS/695/2021**

CE

Issued on: 08/04/2021

Valid until: 07/04/2023

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

SARS-COV-2 Antigen Rapid Test Device(Saliva)

CE

www.cmcmedicaldevices.com

Va multumim!

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www.medplaza.ro
0316.30.66.90