Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **CITEST**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante: **ICOV-502**
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:11/10/2020

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2005804	N	ICOV-502	TEST RAPIDO 2019-NCOV AG	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	10/10/2020		FABBRICANTE	CITEST DIAGNOSTICS INC.			CA
									MANDATARIO	CMC MEDICAL DEVICES & DRUGS S.L.		B93316149	ES

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/29092020.11

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

CITEST DIAGNOSTICS INC.

170-422 Richards Street, Vancouver BC V6B 2Z4 Canada

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 in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2296/2020**

CE

Issued on: 29/09/2020

Valid until: 28/09/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Salmonella paratyphi Antigen Rapid Test Cassette (Feces)
(Model: Cassette)

Salmonella typhi and paratyphi Antigen Combo Rapid Test Cassette (Feces)
(Model: Cassette)

HAV IgG/IgM Combo Rapid TestCassette（WB/S/ P）
(Model: Cassette)

COVID-19 IgG Rapid Test（WB/S/ P）
(Model: Cassette/Strip)

COVID-19 and M.pneumoniae IgG Combo Rapid Test（WB/S/ P）
(Model: Cassette)

COVID-19 and Influenza A+B Antigen Combo Rapid Test
(Nasopharyngeal Swab) (Model: Cassette)

H1N1 Rapid Test（Swab）
(Model: Cassette/ Dipstick)

Influenza A/B +H1N1 Combo Rapid Test (Swab)
(Model: Cassette)

Olanzapine (OZP) Rapid Test Cassette (Urine)
(Model: Cassette/Panel/Dipstick)

COVID-19 IgG/IgM Test Cassette
(Model: Cassette)

EC REP CERTIFICATE

COVID-19 Antigen Test Cassette
(Model: Cassette)

SARS-COV-2 RT-qPCR Assay
(Model: Reagent)

Virus Nucleic Acid Extraction Kit
(Model: Reagent)

Virus Specimen Stabilizer
(Model: Reagent)

CE

【CARATTERISTICHE DI PERFORMANCE】

Sensibilità, specificità e accuratezza

Il COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) è stato valutato con campioni ottenuti dai pazienti. RT-PCR è utilizzato come metodo di riferimento per il test rapido per l'antigene COVID-19 (tampone nasofaringeo). I campioni sono stati considerati positivi se RT-PCR indicava un risultato positivo. I campioni sono stati considerati negativi se la RT-PCR indicava un risultato negativo.

Nasopharyngeal Swab Specimen

COVID-19 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen	Positive	47	1	48
	Negative	5	199	204
Total		52	200	252
Relative Sensitivity		90.4% (95%CI*: 79.0%~96.8%)		
Relative Specificity		99.5% (95%CI*: 97.2%~>99.9%)		
Accuracy		97.6% (95%CI*: 94.9%~99.1%)		

EC Declaration of Conformity

Manufacturer:
Name：CITEST DIAGNOSTICS INC.
Address：170-422 Richards Street, Vancouver BC V6B 2Z4 Canada

European Representative:
Name: CMC MEDICAL DEVICES & DRUGS, S.L.
Address: C/ HoracioLengo No 18, CP 29006, Málaga-Spain

Product Name: COVID-19 Antigen Rapid Test
Model: Cassette
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 15 70 90 90 00

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.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Vancouver on 11/09/2020

CITEST DIAGNOSTICS INC.

Signature: Soar Gao

Name: Soar Gao (Position: General Manager)