People's Republic of China

Medical Device Registration Certificate (In Vitro Diagnostic Reagent)

Registration Certificate No.: 20203400299

Name of registrant	Shanghai Fosun Long March Medical Science Co., Ltd
Address of registrant	No. 830 Cheng Yin Road, Baoshan District, Shanghai, People's Republic of China
Production address	No. 830 Cheng Yin Road, Baoshan District, Shanghai, People's Republic of China
Name of agent	/
Address of agent	/
Product name	Novel Coronavirus (2019-nCoV) Real-time PCR Kit
Packaging specification	32 Tests/Kit, 48 Tests/Kit, 96 Tests/Kit
Main components	2019-nCoV reaction reagent, RT-PCR enzyme, positive control of 2019-nCoV, negative control and internal reference A. (Please refer to the IFU)
Intended use	This kit is used for qualitative detection of suspected cases of novel coronavirus (2019-nCoV) in human throat swab or sputum samples for ORFlab gene of 2019-nCov, N gene and E gene.
Annex	Product technical specification, product manual
Storage condition and validity period	Stored at 2 – 30℃ with protection from light, valid for 6 months (tentatively)
Other content	/
Note	The registrant is required to complete the following after the product is available on the market: 1. This product is used as clinical auxiliary diagnosis of coronavirus and for emergency purpose. The certificate is valid for one year. 2. Company should complete all the registration application and fulfill the management requirement of in vitro diagnosis when renewing the certificate.

Issued by: National Medical Products Administration

Date of approval: 24 Mar 2020

Valid until: 23 Mar 2021