EC DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

nCoV-QS has been classified as General IVDs and is in conformity with the essential requirements and provisions of Council Directive 98/79/EC on *In Vitro* Diagnostic Medical Device.

Manufacturer	**Name :**	**MiCo BioMed Co.,Ltd.**
	Address :	3rd and 4th Floor, 54 Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, Korea, 13449
European representative	**Name :**	**OBELIS S.A**
	Address :	Bd. Général Wahis, 53, 1030 Brussels, Belgium
Brand names		Veri-Q PCR 316
Common names		Novel Coronavirus Detection Kit
Model names		nCoV-QS
Catalogue number		7K105
Component	2x One-Step RT-PCR Master mix :	nCoV-QS-MMGR06
	Primer/Probe mixure1 :	nCoV-QS-PPM1
	Primer/Probe mixure2 :	nCoV-QS-PPM2
	Positive control :	nCoV-QS-PC
	Internal positive control :	nCoV-QS-IPC
	Nuclease free water :	nCoV-QS-DW
Classification		Others, general IVD

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC and EU Harmonized standards(EN ISO 13485:2016/AC:2016, EN ISO 14971:2012, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011) for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

EDMA code	**15.04.40.19**	Coronavirus – NA reagents
Date of issue		25 February 2020
Signature	**Quality Representative :**	Sang-Hyun Lee

CE