wizbiosolutions
THE INNONVATION OF GENOMICS

CE

Declaration of Conformity

MANUFACTURER:
Wizbiosolutions Inc.
A-802, Woolim Lions Valley 2, Sagimakgol-ro 45beon-gil 14,
Jungwon-gu, Seongnam, 13209 South Korea
TEL : +(82) 70-7605-5066 FAX : +(82) 31-624-3066

EUROPEAN REPRESENTATIVE:
MT Promedt Consulting GmbH
Altenhofstr. 80 D-66386St. Ingbert, Germany
+49-6894-581020 / +49-6894-581021
www.mt-procons.com

We, Wizbiosolutions Inc. declare that this device meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. Technical documentation demonstrating compliance as described in Annex III of the IVD Directive 98/79/EC is kept by the manufacturer and can be made available by the authorized representative in Europe.

Product:	WizDx™ COVID-19 CrystalMix PCR Kit
Model Name:	DX1202A, DX1203A
Classification:	Others (Neither Listed in Annex II of IVDD, nor self-testing device)
EDMA code/Term	15 04 40 90 00/ Other Virology – NA Reagents
Standard:	ISO 13485;2016, EN ISO 14971:2012, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13612:2002, EN 62366:2008

Place	**Date**	**Signature**
Seongnam-si, Republic of Korea	2020. 5. 15	

REPUBLIC OF KOREA
WIZBIOSOLUTIONS INC.

Wizbiosolutions Inc.
A-802, Woolim Lions Valley 2, Sagimakgol-ro 45beon-gil 14,
Jungwon-gu, Seongnam, 13209 South Korea
TEL : +(82) 70-7605-5066, FAX : +(82) 31-624-3066
www.wizbiosolution.com