CERTIFICATE

of EU product notification

Reference Number: JH-ERA-18041V00
Issued Date: September 10, 2020

This is certify that, according to In Vitro Diagnostic Medical Device 98/79/EC, we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer:Beijing Hotgen Biotech Co., Ltd
Address: 9th building, No.9 Tianfu Street, Biomedical Base, Daxing District, Beijing, 102600, P.R.China

The Manufacturer declared that the IVD device complies with the Directive including all essential requirements. According to In Vitro Diagnostic Medical Device 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established May 1, 2011, the German Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Devices and has allocated registration numbers shown in:

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
EDMA CODE :15-04-80-90-00
Registration number :DE/CA22/419-1848-IVD

Where the manufacturer affix the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

CE

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