

File No.: **OGYÉI/17106-3/2020**
Registration No.: HU/CA01/17106/20
Subject: Confirmation of Registration
Official: Gábor Szlobodnyik

OFFICIAL CERTIFICATE

Acting in the name of the National Institute of Pharmacy and Nutrition (OGYÉI), applying the § (5) of the nationalized form of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, which is Decree 8/2003 of Ministry of Health, Social and Family Affairs (henceforth: Decree) on the request of Happy Business Services Ltd. (address: 18. Szent István körút, 1137, Budapest, Hungary; VAT number: 22923820-2-41, henceforth: distributor) the registration of the in vitro diagnostic medical device described below has been

confirmed.

Category of the device, applying ISO 15225:2000 is: IVD Devices.
Name of the device: **COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P) ICOV4212**

Name of manufacturer: HANGZHOU CLONGENE BIOTECH CO., LTD.
Code of manufacturer: CN/913301107620252127
Name of distributor: HAPPY BUSINESS SERVICES Zrt.
Code of distributor: HU/22923820241

The official certificate that has registered the data – assuming the uniformity of data – is valid until withdrawal.

The registration is based on the declaration of the manufacturer which confirms that the device has already been registered in a country of the European Union as an in vitro diagnostic medical device, in accordance with the Decree.

OGYÉI fulfilled the request of registration based on the documents above, emphasizing that not every declaration is being examined, therefore registration does not essentially mean the approval of the documentation. This confirmation does not count as an approval.

Appeal of law is, referring to the 116. § (4) of 2016/CL. act (Ákr. act), excluded, the possibility of administrative lawsuit is stated under the 114. § (1) of Ákr.

The judgment described in this official certificate has been made in accordance with the 94–95. § of Ákr., attentively to 7. § (5) of D., which provides scope of authority; applying the denotation described in the edict 28/2015., which is about OGYÉI.

Budapest

Issued by Dr. Kornél Szerdi – Head of Department

Notice sent in an electronic form to the following parties:

1. HAPPY BUSINESS SERVICES Zrt. (18. Szent István körút, 1137, Budapest, Hungary)
2. Archives

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