

Number: OGYÉI/5142-3/2021
Subject: Certification of EUA

CERTIFICATION

Pursuant to **Article 25 paragraph 2 of Act XCV of 2005** on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products and to **Article 4 of Government Decree 488/2020. (XI. 11.)** on Measures Related to the Reliable Supply of Medicinal Products During the Period of State of Danger and upon the Governmental Regulation **1004/2021. (I. 14.)** on the Further Supply of COVID-19 Vaccines, I hereby

CERTIFY

that on the **29th of January 2021**, under no. **OGYÉI/5142-2/2021**, the Hungarian **National Institute of Pharmacy and Nutrition** (seat: 1051 Budapest, Zrínyi St. 3., Hungary) has issued an

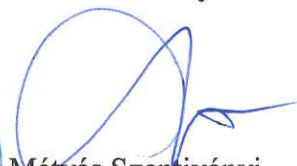
EMERGENCY USE AUTHORIZATION LICENSE

to the **Országos Kórházi Főigazgatóság** (National Directorate General for Hospitals; seat: 1125 Budapest Diós árok 3.) regarding the **SARS-CoV (Vero Cell) inactivated vaccine** which is manufactured by the **China National Biotec Group Company Limited** (Building 2, No. B2 Shuangqiao Road, Chaoyang District, Beijing, 100024, People's Republic of China) on the **Beijing Institute of Biological Products Co. Ltd.** (address: No. 6,9 Boxing 2nd Road, Beijing Economic and Technological Development Zone, Beijing) manufacturing site and which is marketed by **Sinopharm International Hongkong Limited** (Room 1601, Emperor group centre, 288 Hennessy road, Wanchai, HongKong) with the validity of **6 months**, after which it can be extended.

The license guarantees that the Hungarian National Institute of Pharmacy and Nutrition authorized the import of the above mentioned vaccine, which can only be used on humans in the territory of Hungary after drug quality controls were performed on each imported batches by Hungarian laboratories or a quality certificate - regarding the amount and the designated batch of the vaccine - officially certifies that the quality of the batch was controlled and approved by a laboratory in a Member State of the European Economic Area or in an other country which adopted equivalent examination requirements.

The application of the vaccine is under intensified pharmacovigilance control by the Hungarian National Institute of Pharmacy and Nutrition.

Budapest, 3rd of February, 2021.


Mátyás Szentiványi
Director General