Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS

STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

Lepu Medical (Europe) Coöperatief U.A.
Abe Lenstra boulevard 36
8448 JB Heerenveen
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Beijing Lepu Medical Technology Co., Ltd
Building 7-1 No.37 Chaoqian Road, Changping District
Beijing 102200
CHINA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of **VIETNAM**.

This statement is valid until May 26, 2022.

The Hague, September 18, 2020

On behalf of the Minister for Medical Care and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department

Our reference: 20204442
Certificate number: 29017