Declaration of Conformity

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

European Representative:
MedNet GmbH
Borkstrasse 10, 48163 Muenster, Germany

Product Name:
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology)

Classification: Others of ANNEX II of IVDD
Conformity Assessment Route: Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

Signature: 

Name: Lin Changqing
Title: General manager
Place: Beijing, China.
Date of Issue: Aug 27, 2020