# EC Declaration of Conformity

We,

Manufacturer Name: BEIJING BEIER BIOENGINEERING CO., LTD
Address: NO.99, ChuangXin road LuCheng Industrial development zone, HuangCun Town, Daxing district, Beijing, China

as the Manufacturer of
Product Name: COVID-19 Antigen Rapid Test Kit

Model: 20/40 tests per kit
Analyte: SARS-CoV or SARS-CoV-2 Antigen
Classification: Other
Conformity assessment: IVDD 98/79/EEC Annex III

herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

-EN ISO 9001:2015
-EN ISO 13485:2016
-EN 13612-2002
-EN ISO 15223-1-2016
-EN ISO 18113-1-2001
-EN ISO 18113-2-2001
-EN ISO 23640-2015
-EN ISO 14971-2012
-EN ISO 13641:2002
-EN ISO 17511-2003

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

北京贝尔生物工程股份有限公司 1101150288331

Name, Position

September 30, 2020, Beijing, China