



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

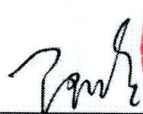
herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

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



Name, Position



September 30, 2020, Beijing, China