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, 102612 Beijing, China

as the Manufacturer of
Product Name: Covid-19 Antigen Rapid Test Kit(Short Nose)
Covid-19 Antigen Rapid Test Kit(Saliva)

Model: 1 test/kit; 5 tests/kit;20 tests/kit
Analytes of the IVD: Detection of SARS-CoV& SARS-CoV-2 Antigen
Classification: Self-testing
Conformity assessment: IVDD 98/79/EEC Annex III, Section 6
CE Certificate No.:1434-IVDD-472/2021

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 13485:2016
- EN ISO 9001:2015
- EN ISO 18113-1:2011
- EN ISO 18113-4: 2011
- EN ISO 14971: 2019
- EN 13612:2002
- EN ISO 15223-1-2016
- EN ISO 23640-2015
- EN ISO 13641:2002
- EN ISO 17511-2020
- EN 13532:2002

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
The manufacturer is exclusively responsible for the declaration of conformity.

Guo Si Xin

Oct.25, 2021, Beijing, China

北京贝尔生物工程股份有限公司
BEIJING BEIER BIOENGINEERING CO., LTD

Name, Position

Digitally signed by Lazari Cristina
Date: 2022.03.11 15:32:02 EET
Reason: MoldSign Signature
Location: Moldova