Jiangsu Bioperfectus Technologies Co., Ltd.
Tel: +86 021-54195536
E-mail: info@bioperfectus.com
Website: www.bioperfectus.com

bioPerfectus technologies

Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit

Declaration of Conformity

Digitally signed by Bolea Petru
Date: 2021.10.17 20:27:51 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer Name: Jiangsu Bioperfectus Technologies Co., Ltd.

Address: 3rd and 4th floors of Building A(G19), 4th floor of Building F(G14), Ground floor of Building G20, Shuaiyu Village, Fuye village, Sixiang town, Taizhou National Medical Hi-tech Development Zone, 225300 Taizhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

European Representative Name: MedNet EC-REP GmbH

Address: Borkstrasse 10 • 48163 Muenster • Germany

Product Name: Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit

Packaging specification: 1T/2T/5T/10T/15T/20T/25T/50T

Analyte: Novel coronavirus (SARS-CoV-2) antigen

Classification: Others device

Conformity Assessment Route: Annex III

We, the manufacturer, declare on our own responsibility the compliance of the above medical device with the applicable requirements of in vitro diagnostic Medical Devices Directive: COUNCIL DIRECTIVE 98/79/EC OF 27 October 1998 CONCERNING in vitro diagnostic MEDICAL DEVICES (IVDD 98/79/EC). All the supporting documents and files are retained under the premises of the manufactures.

Standards Applied: 1. EN ISO 13485:2016 Medical devices-Quality management systems-Requirements for regulatory purposes

2. EN ISO 14971: 2012 Medical devices -Application of risk management to medical devices

3. EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

4. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements (ISO

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18113-1:2009)

5. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

Place, Date of Issue: Taizhou, China, April 6, 2021

Signature:

Name: TUNC MERT SAYIN

Position: Director of International Sales & Marketing Division