

## **Declaration of Conformity**

### **MANUFACTURER**

- Beijing Jinwofu Bioengineering Technology Co.Ltd.
- Address: Address: Room 206, 1st Building, No. 26, Jinyuan Road, Daxing District, Beijing, China
- Tel: 86-010-60216810
- Fax: 86-010-60216810

### **MANUFACTURER SITE**

- Address: Address: Room 206, 1st Building, No. 26, Jinyuan Road, Daxing District, Beijing, China

### **EC-REPRESENTATIVE**

- Osmunda Medical Technology Service GmbH
- Address: Von Oppen-Weg 15, 14476 Potsdam, Germany
- E-mail: eu@osmundacn.com

### **PRODUCT**

- Name: Novel Coronavirus (SARS-COV-2) IgM/IgG Antibody Rapid Test Kit
- Commercial Name: SARS-COV-2 IgM/IgG Antibody Rapid Test Kit
- Generic device term: Detection Card for COVID-19
- Short description and intended use: This product is used for the qualitative testing of new coronavirus SARS-COV-2 IgM/IgG antibody in human serum, plasma or whole blood. Detection of SARS-COV-2 IgM/IgG antibody has the advantages of high sensitivity, early diagnosis, and the ability to determine whether the suspect is infected.
- GMDN code: No GMDN code yet
- Classification: Others

### **CLASSIFICATION**

- Others

(IVD Device other than the ones listed in Annex II -IVDD 98/79 as List A, List B and Self testing)

### **CONFORMITY ASSESSMENT**

Self-declaration of Conformity

### **ROUTE**

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. This declaration is based on conformity to Annex III (excluding Annex III.6). All supporting documentation is retained under the premises of the manufacturer and can be

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available through EU representative.

**STANDARDS APPLIED:**

- ISO 13485: 2016 Medical devices
- EN ISO 18113-2: 2013 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
- EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
- EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- EN 13641: 2015 Fire resistance tests for non-loadbearing elements - Walls
- EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971: 2012 Medical devices. Application of risk management to medical devices
- EN ISO 17511: 2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- EN ISO 11607-1:2014 PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES - PART 1: REQUIREMENTS FOR MATERIALS, STERILE BARRIER SYSTEMS AND PACKAGING SYSTEMS

START OF CE-MARKING: 2020-04-21

PLACE, DATE OR ISSUE: **BEIJING,2020.04.21**

**Registration Information:**

**As stipulated and demanded by the aforementioned directive , the European Databank on Medical Device (EUDAMED) is established as of May.1,2011, the Netherlands competent authority is notified of the manufacturer's Beijing Jinwofu Bioengineering Technology Co.Ltd. IVD medical device and has allocated registration numbers shown:**

**as of today and without any further notice from the respective Competent Authorities, Jinwofu can be considered as the respective devices as officially notified.**

SIGNATURE:



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Name Print: Lang Chen

Position: Manufacture Representative

Date: 2020-04-21