

# DECLARATION OF CONFORMITY



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## *Declaration of Conformity*

**Manufacture Address:** Beijing Lepu Medical Technology Co., Ltd.  
Building 7-1 No.37 Chaoqian Road, Changping District,  
Beijing, 102200, P.R. China

**European Representative:** Lepu Medical (Europe) Cooperatief U.A.  
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The  
Netherlands

**Product information:** SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold  
Immunochromatography)  
Model:  
1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit

**Classification:** Others (not in List A and List B)

**Conformity Assessment Route:** Section 2 to 5 in annex III of IVDD 98/79/EC  
We herewith declare that the above mentioned products  
meet the provisions of the following EC Council Directives  
and Standards.  
All supporting documentations are retained under the  
premise of the manufacturer.

**General Applicable Directive:** DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL of 27 October 1998 on *in vitro*  
diagnostic medical devices

**Standards Applied:** All applicable harmonized standards (published in the  
official journal of the European Communities on 25<sup>th</sup> March  
2020).  
The applicable standards are listed in Annex 1.

**Place, date of issue** Beijing, P.R. China, 3<sup>th</sup>, Sept., 2020

**Signature of Management Representative** *Zhao Mengjie*

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## **Annex 1**

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

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

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic reagents

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

IEC 62366-1:2015 Application of usability engineering to medical devices