

***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)  
**GMDN code:** 64787

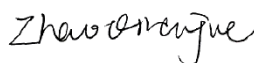
**Conformity Assessment Route:** Section 2 to 5 in annex III of IVDD 98/79/EC  
We herewith declare that the above mentioned products  
meet the provisions of the following EC Council Directives  
and Standards.  
All supporting documentations are retained under the  
premise of the manufacturer. This declaration of conformity  
is issued under the sole responsibility of the manufacturer  
(or installer).

**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, 11<sup>th</sup>, Nov., 2020

**Signature of Management  
Representative**



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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

**Revision history:**

| <b>Version</b> | <b>Revision history</b> | <b>Author</b> | <b>Date</b>                   |
|----------------|-------------------------|---------------|-------------------------------|
| 1/0            | First procedure         | Wenna Li      | 3 <sup>th</sup> , Sept., 2020 |
| 2/0            | Adding GMDN code        | Wenna Li      | 11 <sup>th</sup> , Nov., 2020 |