



## 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 Antibody Test (colloidal gold  
immunochromatography)  
Model: 20 tests per box

**Classification:** Others

**Conformity Assessment Route:** 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 17<sup>th</sup>  
November 2017).

**Place, date of issue** Beijing, P.R. China, March 11, 2020

**Signature of General Director** Qin Xiaowei

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