



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 17th
November 2017).

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

Signature of General Director Qin Xiaowei

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

