

Document No.: CE-DOC-CG29-02

Rev.: 1/0

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: 2019-nCoV 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 25th March

2020).

The applicable standards are listed in Annex 1.

Place, date of issue Beijing, P.R. China, 9th, Nov., 2020

Signature of Management

Representative

Zhaw Oranjue

Beijing Lepu Medical Technology Co., Ltd.

Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China



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 regents

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:

| Version | Revision history | Author | Date |
|---------|------------------|----------|------------------------------|
| 1/0 | First procedure | Wenna Li | 9 th , Nov., 2020 |