LEPU MEDICAL

Document No.: CE-DOC-CG27
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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 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Juli, 2021
Signature of Management Representative	

Beijing Lepu Medical Technology Co., Ltd.
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CE 0197

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 18113-4 :2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing

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

EN ISO 23641:2021 Flexible cellular polymeric materials.

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

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

EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

EN 13532:2003 General requirements for in vitro diagnostic medical devices for self-testing

EN ISO 14971:2020 Application of risk management to medical devices