

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)

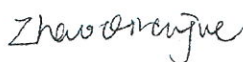
Conformity Assessment Route: Section 2 to 5 in annex III of IVDD 98/79/EC
We herewith declare that the above mentioned products
meet the provisions of the following EC Council Directives
and Standards.
All supporting documentations are retained under the
premise of the manufacturer.

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, Sept., 2020

**Signature of Management
Representative**



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 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:

Version	Revision history	Author	Date
1/0	First procedure	Wenna Li	3 th , Sept., 2020



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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



CE Technical Documentation Review Report

Applicant: **BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.**
Building 7-1, No.37 Chaoqian Road,
Changping District, 102200 Beijing, China

Report Number: **60357276-001**

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III

Product(s): SARS-CoV-2 Antibody Test
(Colloidal Gold Immunochromatography)

Type(s)/Model(s): Cassette, 5 Tests/Kit, 10 Tests/Kit, 20 Tests/Kit

Classification: Other IVD products
(according to manufacturer's declaration)

Examination period: Mar.27.2020

Date of expiry: May.26.2024

Review result: During the examination of the provided Technical Documentation (CE-CG25-1, Revision 1/0, Dated 2020-Mar-20) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.


Yuhong CHEN
Vice General Manager | Medical Greater China
TÜV Rheinland (China) 

To verify the report validity, please send email to: service-gc@tuv.com

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2062714-1

Organization: BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.
Building 7-1, No. 37 Chaoqian Road, Changping District,
102200 Beijing, P. R. China

Scope: Design and Development, Manufacture, Distribution and Service of In-vitro Diagnostic Analyzers and In-vitro Diagnostic Test Kits used in Detection of Cardiac Markers, Blood Analytics, Genetic Testing, Disease Status, Infectious Disease, Cancer Markers and Blood Glucose Monitoring including Meters and Strips including Home Use

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 16805473 008

Effective date: 2020-12-06

Expiry date: 2022-02-12

Issue date: 2020-12-07



Wenxiang Zhang
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Tillystraße 2 · 90431 Nürnberg · Germany