LEPU MEDICAL

Document No.: CE-DOC-CG27
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:	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	Zhao Dongjue

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

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Digitally signed by Azarov Tatiana
Date: 2021.10.17 13:04:45 EEST
Reason: MoldSign Signature
Location: Moldova

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	3th, Sept., 2020

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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 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

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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) Ltd.

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

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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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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