Document Title:	**EU Declaration of Conformity of SARS-CoV-2 Antigen Rapid Tests for Self-testing**
Document Number:	CE- CG36-02
Revision:	1/1
Author:	Zhang Bo
Date:	June 22, 2021

	Superintendent	Date
Written by	Zhang Bo	June 22, 2021
Reviewed by	Li Wenna	June 22, 2021
Approved by	Zhaorongjie	June 22, 2021

REVISION STATUS:

Version	Brief Description of Revision	Author	Date*(DD MM YYYY)*
1/0	New Procedure	Zhang Bo	2021.03.14
1/1	Official version	Zhang Bo	2021.06.22

EU Declaration of Conformity

Manufacturer: Beijing Lepu Medical Technology Co., Ltd.
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SRN: To be registered

European representative: Lepu Medical (Europe) Cooperatief U.A.
Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
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SRN: To be registered

Product: SARS-CoV-2 Antigen Rapid Tests for Self-testing
Model List: Card

REF code	Specifications
CG3601	1test
CG3605	5tests
CG3610	10tests
CG3625	25tests
CG3650	50tests

Applied Standards List: See Annex 1

Classification: self testing

Conformity Assessment Route: IVDD Annex IV excluding (4, 6)

We hereby declare that the above mentioned product meet the provisions of the IVDD 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and Notified Body 0197, TÜV Rheinland LGA Products GmbH, Say Building, Tillystraße 2, 90431 Nürnberg, Germany.

CE 0197

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No: HL 2062714-1	2021-06-21	—	2024-05-26

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer: Beijing Lepu Medical Technology Co., Ltd.

Signed for and on behalf of : Zhao Qianjie
Name : **Zhao Qianjie**
Function (Company) : **Management Representative**
Date : 2021.06.22
Location : **Beijing**

Annex 1 Applied Standards List

The standards applicable for this product are listed as below:

Standard No.	Standard Name
EN ISO 13485:2016+AC:2018	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 13641:2002	Elimination or Reduction of Risk of Infection Related to In Vitro Diagnostic Reagents
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 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). 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 13612:2002/AC:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 13532:2002	General Requirements for In Vitro Diagnostic Medical Devices for Self-testing
EN 13975:2003	Sampling Procedures Used for Acceptance Testing of In Vitro Diagnostic Medical Devices-Statistical Aspects