
Document Title: **EU Declaration of Conformity of SARS-CoV-2 Antigen Rapid Tests for Self-testing**

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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 | Zhao Wenjie | 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 |
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18-CHP-202107

EU Declaration of Conformity

Manufacturer: Beijing Lepu Medical Technology Co., Ltd.

Address: No. 37, Chaoqian Road, Changping District, Beijing, 102200, China

Tel.: +86-10-80123111 **Fax:** +86-10-80123100

SRN: To be registered

European representative: Lepu Medical (Europe) Cooperatief U.A.

Address: Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands

Tel: +31-515-573399 **Fax:** +31-515-760020

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

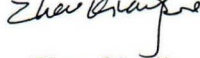
Conformity Assessment Route: IVDD Annex IV excluding (4, 6)

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 : 
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 |