Kingline GmbH
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LEPU MEDICAL SARS-CoV-2 ANTIGEN RAPID TEST

SCHNELLTEST ZUR EIGENANWENDUNG

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PRODUKTINFORMATIONEN

Test-Kit

Packungsinhalt

Verfügbar als

5er Pack

10er Pack

25er Pack

PRODUKTEIGENSCHAFTEN

- Einfache und sichere Anwendung
- Lagerung bei Raumtemperatur
- Klares Ergebnis über Farbstreifen
- Probenentnahme über Tupfer
- Test zur Eigenanwendung

VPE	5er/10er/25er (150 Stk./380 Stk./450 Stk.)
Maße je Karton	59x30x49 cm L/B/H
Gewicht je Umkarton	8,5 kg/11,5 kg/13,5kg
Kartons je Palette	3000/7600/9000 Stk.
Maße je Palette	120x80x200 cm L/B/H
Gewicht je Palette	185 kg/245 kg/285 kg

Herstellerzertifizierung	EN ISO 13485:2016
Art der Probe	Vorderer Nasenabstrich
Auswertungsdauer	15 Min.
Zertifizierung	CE-0197
Diagnostische Sensitivität	95,5%*
Diagnostische Spezifität	100%*

* Die Sensitivität/Spezitivität gibt LEPU in der Gebrauchsanweisung wie folgt an: Die diagnostische Sensitivität und die diagnostische Spezifität des Produkts lagen bei 95,9 % (90,8-98,2 %) bzw. 100 % (96,3-100 %).

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PRODUKTINFORMATIONEN

ANLEITUNG

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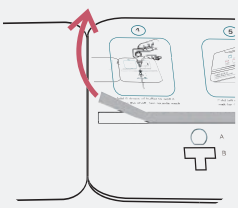
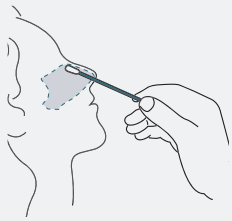
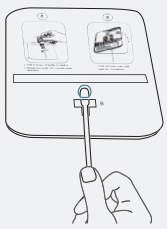
- Die Testkarte muss innerhalb **1 Stunde nach dem Öffnen** des versiegelten Beutels verwendet werden
- Alle Teile des Testkits sollten Raumtemperatur haben

② 

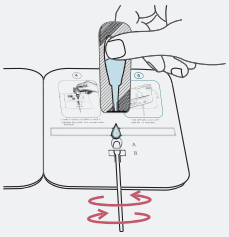
- Testkarte aufklappen
- Testkarte auf eine feste, gerade Unterlage legen
- Folie über dem Klebestreifen K entfernen

③ 

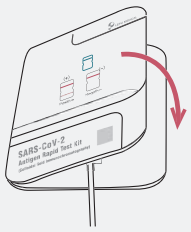
- Tupfer zuerst **2-3 cm** in die eine Nasenhöhle stecken
- Tupfer **5 Mal** im Kreis drehen
- Dann Vorgang genauso **in der zweiten Nasenhöhle wiederholen**

④ 

- Tupfer am Stiel halten und den Tupferkopf von unten durch die **Öffnung B** in **Vertiefung A** schieben
- Den Tupferkopf dabei nicht berühren

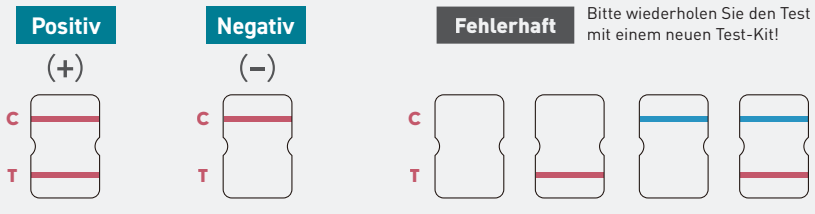
⑤ 

- Kopf von Lösungsfläschchen vorsichtig abdrehen und **6 Tropfen der Lösung** auf den Tupferkopf in Vertiefung A geben
- Danach den Tupfer am Stiel **2 Mal in jede Richtung drehen**

⑥ 

- Karte schließen, mit **Klebestreifen K zukleben** & vorsichtig zusammendrücken
- Ergebnis **nach 15 Minuten** (nicht später als 20 Min.) auf der Vorderseite der Karte im **Ergebnisfenster** ablesen
- Karte während der Wartezeit nicht mehr bewegen!

ERGEBNISKONTROLLE



EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.:	HL 2062714-1
Manufacturer:	BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD. Building 7-1, No. 37, Chaoqian Road, Changping District 102200 Beijing P.R. China
Products:	Blood Glucose Monitoring Systems Blood Glucose Test Strips SARS-CoV-2 Antigen Rapid Tests for self-testing

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.:	190131772 110
Effective date:	2021-06-21
Expiry date:	2024-05-26
Issue date:	2021-06-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl. Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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

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	Zhang Yongke	June 22, 2021

EU Declaration of Conformity

Manufacturer: Beijing Lepu Medical Technology Co., Ltd.
Address: No. 37, Chuangxin Road, Changping District, Beijing, 102208, 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 (5, 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, Süy Building, Tillystraße 2, 90431 Nürnberg, Germany.

CE 0197

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No: HL 206271 4 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 I 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 Reagents
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