KINGLINE GMBH

BEIER NASAL
CODIV-19 ANTIGEN-SCHNELLTEST-KIT

Zertifiziert und Evaluiert

Zuverlässig sehr genaue Ergebnisse

Persönliche Experten-Beratung

verkauf@kingline.de | +49 (0) 9135 - 5718390

Version: 1.0 | Freigabe: 31.01.2022

Kingline GmbH | Gewerbering 32a | 91341 Röttenbach

DETAILINFORMATIONEN

CE-Kennzeichnung	CE-1434
AT-Nummer	AT1285/21
Art der Probe	Anterior Nasal
Anwendungsart	Laien
LoD-Wert	1,3 x 10^2 TCID 50/ml
Diagnostische Sensitivität	96,5 % (95% CI:93,7% ~ 99,3%)
Diagnostische Spezifität	99,7% (95% CI:99% ~ 99,6%)
Haltbarkeit (ab Produktionsdatum)	18 Monate
Verfügbare Sprachen des Handbuchs	Englisch, Deutsch, Polnisch*, Tschechisch*

* Für Verfügbarkeiten wenden Sie sich bitte an einen unserer Vertriebsmitarbeiter

LOGISTIKDATEN

VPE	700 Stk. (20er-Packungen)
VPE Gewicht	12 kg
VPE Maße (B x H x T)	55x45x35 cm
EPAL Gewicht	207 kg
EPAL Maße (B x H x T)	120x80x195 cm
Lagertemperatur	min. 4 °C; max 30°C
Vereinzelbar	ja

DISTRITBUTION

Hersteller	Beijing Beier Bioengineering Co., Ltd. No.99 Chuangxin Road, Lucheng Industrial Development Tone, Huangcun Town, Daxing District, Beijing, P.R. China
EC-REP	MedNet GmbH Borkstrasse 10 48163 Münster, Deutschland

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CERTIFICATE

EC Certificate No. 1434-IVDD-472/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Beijing Beier Bioengineering Co., Ltd
No. 99 Chuangxin Road, LuCheng Industrial Development Zone, HuangCun Town, Daxing District, 102612 Beijing, Pekin

in vitro diagnostic medical devices
for self-testing

Covid-19 Antigen Rapid Test Kit (short Nose) Ref. No. 600485
Covid-19 Antigen Rapid Test Kit (Saliva) Ref. No. 600486

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 20.10.2021 to 27.05.2024

The date of issue of the Certificate: 20.10.2021

The date of the first issue of the Certificate: 20.10.2021

CE 1434

Issued under the Contract No. MD-63/2021
Application No: 126/2021, 127/2021
Certificate bears the qualified signature.
Warsaw, 20.10.2021
Module A1
FBM-30-E_10

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.20 12:43:36 +02'00'

Vice-President

EC Declaration of Conformity

We,
Manufacturer Name: BEIJING BEIER BIOENGINEERING CO., LTD
Address: NO.99, ChuangXin road LuCheng Industrial development zone, HuangCun Town, Daxing district, 102612 Beijing, China

as the Manufacturer of
Product Name: Covid-19 Antigen Rapid Test Kit(Short Nose)

Model: 1 test/kit; 5 tests/kit;20 tests/kit
Analytes of the IVD: Detection of SARS-CoV& SARS-CoV-2 Antigen
Classification: Self-testing
Conformity assessment: IVDD 98/79/EEC Annex III, Section 6
CE Certificate No.:1434-IVDD-472/2021

herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

- EN ISO 13485:2016
- EN ISO 9001:2015
- EN ISO 18113-1:2011
- EN ISO 18113-4: 2011
- EN ISO 14971: 2019
- EN 13612:2002
- EN ISO 15223-1-2016
- EN ISO 23640-2015
- EN ISO 13641:2002
- EN ISO 17511-2020
- EN 13532:2002

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

The manufacturer is exclusively responsible for the declaration of conformity.

Guo Si Xin

北京贝尔生物工程股份有限公司
BEIJING BEIER BIOENGINEERING CO., LTD

Oct.05 20, 2021, Beijing, China

Name, Position