NASOCHECKcomfort

DATA SHEET SARS COV-2-ANTIGEN RAPID TEST KIT FOR DOMESTIC USE

General information		Packaging data	
Model	NASOCHECKcomfort	Quantity per pack (coulour box)	5 tests
Classification	SARS-CoV-2 Antigen Rapid test kit (colloidalGold Immunochromato-graphy) for professional and domestic use (approved by BfArM/5640-S-253/1)	Quantity PCS per CTN	325
		Quantity colour boxes per CTN	65
		EC REP	Lepu Medical (Europe) Coop. U.A. Abe Lenstra Boulevard 36 8448 JB Heerenveen, Netherlands
		IMPORTER	tbc*
Type	IVD (others)	CTN nett weight	10.2kg
specimen	Anterior nasal swab	CTN Gross weight	11.2kg
Clinical sensitivity	95.06%	1 pack (5pcs) weight	157g
Clinical specificivity	99.62	CTN size	59*31.5*48cm
CI 95% sensitivity	91.57%-97.15%	1 pack (5pcs) size	199*140*39mm
CI 95% specivitivity	97.89%-99.93%	EAN code	6-921807-601488*

Approval data		Approval dates	
Reference standard(EU)	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices Section 2 to 5 in annex III of IVDD 98/79/EC All supporting documentations are retained under the premise of the manufacturer.		
CE marking(EU)	By Beijing Lepu Medical Technologies Co, Ltd	Date issued	2020-09-03
(1) Common list of COVID-19 rapid antigen tests	*The EU common list lists COVID-19 rapid antigen test kits* of which results are mutually recognised in all EU countries based on a common standardised set of data to be included in COVID-19 test result certificates.	Date listing	2021-02-17
(2) PEI test report	Paul Ehrlich Institut *Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests*	Date issued	2021-01-26
(3) Analysis Specificity Investigation Report	By Lepu Medical technology Co, LTD *-cross-reaction investigation* *-pathogen interference investigation*	Date issued	2020-09-26

* confirmed after order confirmation

(4) Johner Institut Domestic use investigation report	"Ergebnisse und Analyse"	Date Issued	2021-01-27
(5) EU CE Declaration of Co n-formity	CE-DOC-CG27 REV 1/0	Date issued	2020-09-03
Approval bodies			
Paul Erlich Institut		*Paul-Ehrlich-Institut* Federal Institute for Vaccines and Biomedicines Paul-Ehrlich-Str. 51-59 63225 Langen -Germany	
Johner Institut		*Johner Institut GmbH* Reichenaustr. 1 78467 Konstanz-Germany	
BfArM #		*Bundesinstitut fur Arznaimittel und Medizinprodukte* Emergency authorisation to use Lepu Medical SARS-CoV-2 Antigen Rapid Test Kit for Self-testing. Kurt-Georg-Kiesinger-Allee 3 53175 Bonn	
(6) TUV Rheinland NB0197 *CE0197 Expected end April/beginning of May 2021*		*CExxxx Certification* for IVDD98.79/EC AnnexIV without section 4 and 6, product expansion SARS-CoV-2 Antigen Rapid Test Kit for Self-testing