ZERTIFIKAT ◆ CERTIFICAT ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV including (4,6) - device for self-testing

No. V1 18 02 03496 002

Manufacturer: Beijing Lepu Medical Technology Co. Ltd
Building 7-1 No. 37 Chaoqian Road, Changping District,
Beijing, 102200, P.R. China

EC - Representative: Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448, JB, Heerenveen,
The Netherlands

Product Category(ies): Product for determination of infection markers

The Certificate Body of TUV SUD Product Services GmbH declares that the aforementioned manufacturer has implemented a quality assurance system to design, manufacture and final inspection of the respective devices/ device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance.

Report No.: SIN_5010329172_CC2_2020

Valid from: 2020-03-13
Valid until: 2023-06-27

Date, 2020-03-13

Stefan PreiB

TUV SUD Product Services GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Model(s):

In-Vetro Diagnostic Medical Device for Detection of SARS-CoV-2 Antibody (colloidal gold immunochromatography)
Model: COVID19 INSTATEST (Self-testing: 1 test per box)

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