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CE Technical Documentation Review Report

Applicant:	**BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.** Building 7-1, No.37 Chaoqian Road, Changping District, 102200 Beijing, China
Report Number:	**60357276-001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	SARS-CoV-2 Antibody Test (Colloidal Gold Immunochromatography)
Type(s)/Model(s):	Cassette, 5 Tests/Kit, 10 Tests/Kit, 20 Tests/Kit
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.27.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CE-CG25-1, Revision 1/0, Dated 2020-Mar-20) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

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To verify the report validity, please send email to: service-gc@tuv.com