

质量第一,管理优先 建和谐企业,创协合品牌 Quality First, Management Priority. Building Harmonious Enterprise, Creating Singclean Brand

Notification of Shelf Life

To whom it may concern

We, Hangzhou Singclean Medical Products Co., Ltd. with address located at No.125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 310018, as the manufacturer of the Self-testing IVD Medical Devices COVID-19 Test Kit (Colloidal Gold Method), hereby state as follows:

We proposed a change of Shelf Life of COVID-19 Test Kit (Colloidal Gold Method) (for self-testing) from 1 year to 2 years, and it was approved by the Notified Body POLISH CENTRE FOR TESTING AND CERTIFICATION (No. 1434) at 2022.05.27.

The Product has no changes, and the stability verification for 2 years is on the Product manufactured before the approval date.

Hangzhou Singclean Medina Products Co., Ltd.