

## Statement

We, **SAFECARE BIOTECH (HANGZHOU) CO., LTD.** Hereby declare to extend the shelf life of COVID-19 Antigen Rapid Test Kit(Swab) (Ref: COV Ag-6012H) to 24 months based on the latest real time stability study data.

According to the MDCG 2022-06 *Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR*, extension or reduction of shelf life of a non-sterile device is non-significant change and we had informed this change to notify body- PCBC 1434 and EU Rep.- NIC GmbH.

Sincerely yours,

Safecare Biotech (Hangzhou) Co., Ltd.

