Medical Device Administrative Control System <u>Listing of Rapid Antigen Test for COVID-19</u>

Medical Device Administrative Control System (MDACS) is a voluntary system established by the Department of Health (DH) in 2004 to pave the way for implementing the long-term statutory control of medical devices. The MDACS consists of a number of control measures, including

Medical Device Listing System Traders
Listing System

(including local responsible person, local manufacturer, importer and distributor) Medical Device
Safety Alerts &
Adverse Events
Reporting
System

The purpose of the listing system is to ensure the listed medical devices in the Hong Kong market have met the safety, quality and performance requirements, so as to protect the public health. Moreover, the Government has accepted the Rapid Antigen Test for COVID-19 (RAT kits) that are listed under MDACS, and the details of the listed RAT kits are uploaded to the website of the Medical Device Division (MDD) of DH. Therefore, we recommend medical device traders to participate in the MDACS and apply for listing their RAT kits.

For details of the MDACS, please visit MDD's website:

www.mdd.gov.hk



