



ANNOUNCEMENT UPDATE

UPDATE ON THE RE-REGISTRATION REQUIREMENTS FOR COVID-19 TEST KITS UNDER THE EXEMPTION FROM THE CONFORMITY ASSESSMENT PROCESS BY THE CONFORMITY ASSESSMENT BODY (CAB)

Dear All Medical Device Industry Stakeholders,

The Medical Device Authority (MDA) extends its highest regards to all valued stakeholders.

The Medical Device Authority (MDA) wishes to inform all stakeholders that the **Exemption from the Conformity Assessment Process by the Conformity Assessment Body (CAB) for Registration of COVID-19 Test Kits** is no longer applicable following the withdrawal of the circular letter on **23 February 2024**.

Accordingly, any subsequent registration application for a COVID-19 test kit shall comply with the current registration requirements and undergo conformity assessment by a Conformity Assessment Body (CAB) in accordance with the applicable MDA guidance documents, including **MDA/GD/0031**, **MDA/GD/0068**, and **MDA/GD/0070**. A valid **CAB Conformity Assessment Report** and **Certificate of Conformity** shall be submitted as part of the registration application.

For COVID-19 test kits that already have an existing registration record in **MeDC@St**, the establishment may submit a **re-registration application through the existing registration record** according to the applicable conformity assessment pathway below:

| Pre-Market Approval | Applicable Conformity Assessment Pathway | Required CAB Report |
|---------------------|---|---|
| Yes | INITIAL Certification via Verification Pathway | Initial Certification Report in accordance with MDA/GD/0068/MDA/GD/0070 |
| No | Full Conformity Assessment | Full Conformity Assessment Report in accordance with MDA/GD/0031 |

Thank you.

For further information and inquiries, please contact:

Pre-Market Control Division

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