



## ANNOUNCEMENT UPDATE

### SUBMISSION OF MEDICAL DEVICE RE-REGISTRATION APPLICATIONS VIA MeDC@St 2.0+ SYSTEM ONE (1) YEAR PRIOR TO CERTIFICATE EXPIRATION DATE

Dear **All Medical Device Industry Stakeholders**,

Greetings from the Authority!

The Medical Device Authority (MDA) hereby reminds all licensed establishments of the procedural requirements governing the re-registration of medical devices in Malaysia.

In accordance with the **Medical Device Guidance Document** titled: [Guide for Medical Device Establishment – Conformity Assessment by Way of Verification & Submission of Medical Device Registration in MeDC@St \(Document No. MDA/GD/0070, March 2025 – First Edition\)](#), re-registration applications shall be submitted via the **MeDC@St 2.0+ online system**.

The re-registration function will be made available **exactly one (1) year prior to the expiration date** of the current registration certificate, allowing ample time for establishments to prepare and submit their applications.

As part of MDA's continuous efforts to strengthen regulatory enforcement and system automation, the **MeDC@St 2.0+ system is configured to automatically deactivate registration certificates upon their expiry**. Once the registration certificate has expired, **the system will not allow any re-registration application submissions, including applications that were created prior to the certificate expiry date but were not submitted in time**.

In such cases, establishments shall be required to submit a **new registration application**, which will be subject to the full conformity assessment process under the **Medical Device Act 2012 (Act 737)**. Establishments are therefore **strongly advised to plan and manage their re-registration and change notification activities well in advance** to avoid any disruption to regulatory compliance or market access.

The MDA appreciates the continued cooperation and commitment of all stakeholders in supporting the Authority's efforts to ensure the safety, quality, and sustained availability of medical devices in Malaysia.

Thank you.

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#### Revision History:

- **Initial Release:** 17<sup>th</sup> May 2024
- **Revision 1 (Current):** 5<sup>th</sup> June 2025
  - Updated to align with MDA/GD/0070 (March 2025 – First Edition); added clarification that the system will not allow submission of any re-registration application once the certificate has expired, including unsubmitted drafts.