



ANNOUNCEMENT UPDATE

MDA APPROACH FOR NEW REGISTRATION OF MEDICAL DEVICES WITH EXPIRED EC CERTIFICATES

Dear **All Medical Device Industry Stakeholders**,

Greetings from the Authority!

The Medical Device Authority (MDA) extends its compliments to all stakeholders.

This announcement serves to inform the industry of an updated regulatory approach, as outlined in the recently published [MDA Circular Letter No. 1 Year 2025](#), concerning the use of expired EC Certificates for the purposes of new medical device registration in Malaysia.

The EC Certificate (CE Marking), issued pursuant to Directives 90/385/EEC, 93/42/EEC, and 98/79/EC, continues to be recognized by the MDA as a valid form of approval for the purposes of conformity assessment via the verification process with a registered Conformity Assessment Body (CAB), as stipulated under the current regulatory framework.

Ordinarily, such certificates and associated declarations of conformity must remain valid at the time of submission. Nevertheless, in consideration of the ongoing and unpredictable challenges associated with the transition to the European Union Medical Device Regulation (EU MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), the MDA has adopted a temporary and conditional approach to facilitate continued market access and ensure uninterrupted device availability. Accordingly, expired EC Certificates issued under the aforementioned Directives may be accepted for conformity assessment by way of verification with a registered CAB, **provided that the following conditions are strictly fulfilled:**

- a. The medical devices continue to comply with the applicable provisions of Directive 90/385/EEC, 93/42/EEC, or 98/79/EC;
- b. There are no significant changes in the design or intended purpose of the device; and
- c. The devices do not pose an unacceptable risk to the health or safety of patients, users, or other persons, nor to public health.

In addition, applicants are required to submit one or more of the following **supporting documents** as part of the verification process:

- d. A formal letter from the relevant national competent authority confirming the grant of a derogation from the applicable conformity assessment procedure; and/or
- e. A confirmation letter issued by the notified body attesting to the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement prior to certificate expiry; and/or
- f. An audit report evidencing that the manufacturer has implemented a Quality Management System (QMS) in compliance with the requirements of the EU MDR or IVDR; and/or
- g. A declaration letter issued by the notified body confirming a delay in the issuance of a new certificate; and/or
- h. A confirmation letter from the notified body acknowledging receipt of the application for conformity assessment.

The MDA remains committed to ensuring regulatory flexibility, without compromising patient safety, during this transitional period. Stakeholders are advised to adhere strictly to the requirements outlined above and to remain informed of future updates issued by the Authority.

Thank you.

Pre-Market Control Division (BKPP)

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Revision History:

- **Initial Release:** 27th June 2023
- **Revision 1:** 22nd August 2024
- **Revision 2 (Current):** 5th June 2025
 - Circular reference updated to MDA Circular Letter No. 1 Year 2025.
 - Scope limited to new registration submissions only.
 - Removal of reference to re-registration and Class B IVD self-declarations.
 - Streamlined document requirements in line with current EU regulatory transition procedures.