ANNOUNCEMENT UPDATE:
MDA APPROACH FOR NEW AND RE-REGISTRATION OF MEDICAL DEVICES WITH EXPIRED EC CERTIFICATES AND SELF-DECLARED CLASS B IVD

Dear **Medical Device Industry Stakeholders**,

Greetings from the Authority!

EC Certificate (CE Marking) pursuant to Directive 90/385/EEC, 93/42/EEC, 98/79/EC or EC declaration of conformity (Section 1 to 5 of Annex III) for IVD medical device issued in accordance with Directive 98/79/EC (only applicable for class B IVD medical device in accordance with Medical Device Regulation 2012) is one of the approval types that is recognised by Medical Device Authority (MDA) for conformity assessment procedure by way of verification process for the purpose of medical device registration in Malaysia. This requirement is prescribed in the Circular Letter of the MDA No.2 Year 2014.

In principle, the certificate and declaration of conformity shall be valid during the new registration and re-registration submission. However, due to the unpredictable timeline and issues with regards to the transition to the EU MDR and IVDR, and to ensure continuous supply of the medical device in the market, MDA has taken an approach to **allow expired EC Certificates pursuant to Directive 90/385/EEC, 93/42/EEC, 98/79/EC or a declaration of conformity pursuant to Directive 98/79/EC** (only applicable for class B IVD medical device in accordance with Medical Device Regulation 2012) to be utilized for **conformity assessment procedures by way of verification** process with the registered conformity assessment body (CAB) if the following conditions are met:

a. The devices continue to comply with Directive 90/385/EEC, 93/42/EEC or 98/79/EC; and
b. There are no significant changes in the design and intended purpose; and
c. The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Additionally, the following supporting documents shall be provided for conformity assessment by way of verification process:

d. A formal letter from the national competent authority that has granted a derogation from the applicable conformity assessment procedure; and/or
e. A confirmation letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement prior to the expiration of the certificate; and/or
f. An audit report as evidence that the manufacturer has put in place a quality management system in accordance with MDR and IVDR; and/or
g. A declaration letter issued by the notified body stating the delay in the issuance of a new certificate; and/or
h. A self-declaration by the manufacturer confirming that the conditions for the MDR or IVDR extension are fulfilled, stating the end date of the transition period. Such self-declaration should clearly identify the devices covered by the extension and certificates concerned. The self-declaration letter shall be supported by a confirmation letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment.

Thank you.
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