MDA Approach on Expired EC Certificate for New Registration and Re-registration of Medical Device

- MDA has taken an approach to allow expired EC Certificate to be used for conformity assessment procedure by way of **verification** process with the registered CABs if the following conditions are met:

1. The devices continue to comply with Directive 90/385/EEC and 93/42/EEC; and
2. There are no significant changes in the design and intended purpose; and
3. 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:

4. A formal letter from the national competent authority that has granted a derogation from the applicable CA procedure; **and/or**
5. A confirmation letter issued by the NB stating the receipt of the manufacturer's application for CA & the conclusion of a written agreement prior to the expiration of the certificate; **and/or**
6. An audit report as evidence that the manufacturer has put in place a QMS in accordance with MDR; **and/or**
7. A declaration letter issued by the NB stating the delay in the issuance of a new certificate.

Announcement Reference: MDA Approach on expired EC Certificate for New Registration & Re-registration of Medical Device – updated 26 June 2023

Medical Device Authority Malaysia