



MEDICAL DEVICE RE-REGISTRATION APPLICATION: IMPLEMENTATION OF INITIAL MDA RESPONSE WITHIN 14 WORKING DAYS

In accordance with the decision reached at the MDA-*Industry Collaborative Committee* (MICC) Bil.1/2024 dated 6th Feb 2024, it was agreed that MDA will provide initial response to applications for medical device **RE-REGISTRATION** within **14 working days** (from the date the application is assigned to the reviewer).

The elements that will be checked during the initial response are as follows:

1. Accurate risk classification of medical device
2. Appropriate grouping of medical devices
3. An updated clinical evaluation report or performance evaluation report
4. An updated quality management system (QMS)
5. An updated conformity assessment report and a valid certificate
6. An updated declaration of conformity
7. An updated post market surveillance and vigilance report for the past 3 to 5 years.

Important Notes:

- Incomplete applications without the above elements will be returned **once** to the applicant to complete it and/or provide the information and/or particulars and/or documents within **30 working days**.
- The application **will be rejected** if any information, particulars or documents as requested are not provided to the MDA within 30 working days or the application is returned without the requested information, particulars or documents.
- However, this will not affect the right of the applicant to make a new application and application fee is not refundable.

Thank you.

Pre-Market Control Division
Medical Device Authority
Ministry of Health Malaysia
13th Feb 2024