General Directive of the Minister of Health No. 1/2024 Pursuant to the Provisions of the Medical Device Authority Act 2012 [Act 738]: Implementation of the Policy of One License For Each Establishment Role

MDA would like to inform the General Instruction of the Minister of Health No. 1/2024 According to the Provisions of the Medical Devices Authority Act 2012 [Act 738]: The implementation of the One License For Each Establishment Role policy has been uploaded to the MDA website and will come into effect from 18 March 2024 in accordance with the decision made in the PBPP Members' Meeting No. 1/2024.

This matter is also in line with the announcement that was made on 14 September 2021 referring to the Cancellation of the Medical Devices Authority's (PBPP) Circular Letter No. 1/2014 related to establishments that act as authorized representatives *(*AR) and establishments that carry out various activities.

In connection with the enforcement of this General Directive of the Minister of Health, establishments can no longer combine license applications for the activities of manufacturers, authorized representatives, importers or distributors under the same license.

In line with that, establishments that have combined more than one role in one license before that want to renew their license, can apply for the license renewal application procedure from the Licensing Branch, Pre-Market Control Division for consideration of approval to get a fee refund based on the amount of eligibility actual license renewal fee in accordance with the Fifth Schedule, Medical Devices Regulations 2012.

The General Instructions can be downloaded from the MDA website, and through the following link CLICK HERE .

Establishments can contact the Licensing Branch, Pre-Market Control Division via email license-unit@mda.gov.my to get more information.

Thank you

Chief Executive

Medical Devices Authority

15hb. April, 2024

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