ANNOUNCEMENT RELATED CUSTOM-MADE MEDICAL DEVICE

Announcement: Clarification on the regulation of Dental Products

The Medical Device Authority (MDA) wishes to clarify that dental products, including but not limited to crowns and aligners, are medical devices that fall under the regulatory requirements of the **Medical Device Act 2012 [Act 737]**.

Accordingly, all local companies including laboratories involved in the manufacturing of such dental products must ensure that these devices are registered with the Authority to comply with Act 737.

In cases where the dental products meet the criteria for custom-made medical devices, **manufacturers** may submit an exemption application directly to the Authority. This exemption is applicable only when the specific requirements of a custom-made device are fulfilled.

This announcement serves to reinforce the importance of regulatory compliance and to support the safe and effective use of dental products in Malaysia.

Date of published: 11-Nov-2024