

PRODUCT CLASSIFICATION APPLICATION

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Objective

To determine whether a product is Medical Device or non-Medical Device

Classification Criteria

- The **primary intended purpose** of the product,

- The **primary mode of action/the principal mechanism of action** by which the claimed effect or purpose of the product is achieved
 - i. **Medical Device** is based on function by **physical means** eg; mechanical action, creation of a physical barrier or replacement or support of organ or body function,
 - ii. **Drug** is based on pharmacological, immunological or metabolic action in/on the body.

- **Active ingredient, indication and pharmaceutical dosage form** (those are the main criteria for classification of the drugs), kindly refer to [Medical Device – Drug – Cosmetic Interphase](#) (MDDCI) products

- Classification of the product/combination product or similar product/similar combination product in the **reference countries**. The reference countries are US, EU, Canada, Australia and Japan.

- The primary mode of action/the principal mechanism of action may be deduced from the scientific data and the manufacturer's **labelling and claims**.
 - i. The claims made for a product, in accordance with its mode of action may represent an important factor for its qualification as a medical device.

Payment

- Circular Letter of the Medical Device Authority No. 5 Year 2016: The Medical Device Authority Meeting No. 3/2016 has decided to set the policy for imposition of charges or fees for product classification. The product classification will be charged RM300.00 per application effective on 1st December 2016.

- All fees shall be paid through bank draft. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA;
 - i. The bank draft must be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and sent to MDA office;
 - ii. Information on reference number and Phone No. of the applicant must be written at the back of the bank draft but not in the table section;
 - iii. Complete submission for product classification application upon clear payment will be processed within 14 -21 working days. However, the time frame may take longer if the product needs to be further discussed.

FLOWCHART FOR PRODUCT CLASSIFICATION APPLICATION PROCESS

