Product Classification Application

This application is to determine whether the product is classified as a medical device or non-medical device product by the definition of medical device under Act 737. Any person wishing to apply for Product Classification Application please CLICK HERE for online application.

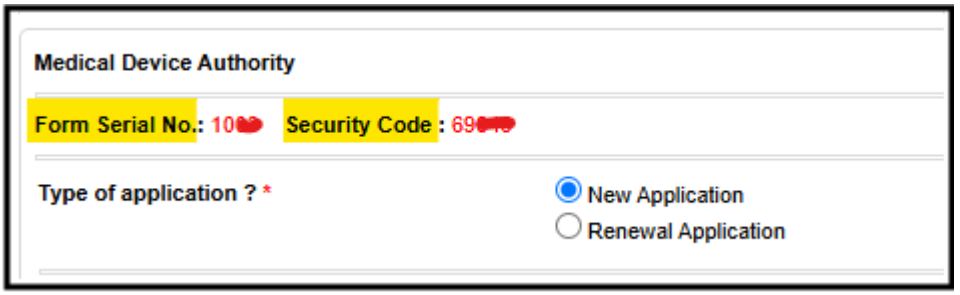
ANNOUNCEMENT:

Conditions and fee structure:

- Product Classification is not intended to determine the Risk and Rules Classification of the medical devices. No information of Risk and Rule will be stated on the product classification letter.
- One application is only for 10 products with same product name, intended use, and manufacturer. If you are applying for more than 10 products, please apply in another separate application form. Every model number or unique identifier counts as one product.
- All applications will be charged RM 300 per submission for 2 years validity date

Step for Application:

1. Create New Application Form: A unique Form Serial No. and Security Code will be generated for your application. Please save these details to track your application status later.



2. Type of application: if a new application, please click New application. If application is to renew the previous product classification letter, please click Renewal Application;
3. Section 1 is for applicant details or organization information;
4. Section 2 is for details of manufacturer;
5. Please fill the document on Product Classification Template (CLICK HERE) and upload into SECTION 3 - SUPPORTING DOCUMENTS for document to be uploaded.
6. Required documents to be uploaded:

Documents	**New Application**	**Renewal Application**
Product Classification Template	Yes	Yes
Product information of intended purpose, mode of action	Yes	Yes

Product label (indicating product name and manufacturer)	Yes	Yes
Product leaflet / brochure / catalogue (contain description, intended use)	Yes	Yes
User manual, Instruction for use, Packaging Insert	Yes	Yes
Manufacturing Process (For Human Tissue Based Products) (if applicable)	Yes (if applicable)	Yes (if applicable)
Previous Product Classification Letter - for RENEWAL	No	Yes
Declaration of Conformity (if applicable)	(if applicable)	(if applicable)
Quality Management System (QMS) Certificate or equivalence (if applicable)	(if applicable)	(if applicable)
Premarket Approval (if applicable)	(if applicable)	(if applicable)

(And any other additional information, particulars /documents as may be required)

7. Once status is ‘Payment Advice’ in PC online application system. Payment invoice will be uploaded in the BayarNow system in 3 working days;
8. Certificate issuance will be emailed within 30 working days upon complete information or document submission.

PAYMENT:

- All fees shall be paid via BayarNow system. CASH and BANK DRAFT WILL NOT BE accepted. We will not be responsible for the cash sent or BANK DRAFT brought to MDA;
- For instructions on how to use BayarNow, please download the user manual at the following link, MDA BayarNow User Manual.

Additional information

During Screening, additional information, particulars and documents requested by the Authority on the application shall be submitted by the applicant within 5 working days from the date of return of application. If the additional information, particulars or document of the application is not given by the applicant within the time granted (5 working days), the application shall be deemed to be withdrawn and shall not be further proceed with, but without affecting the right of the applicant to make a fresh application.

Complete submission for product classification application will be processed within 30 working days.

The above requirement is subject to change from time to time.

Frequently Asked Questions (FAQ)

Questions	Answer
Does the classification letter state the risk level of my medical device?	No. Product classification only determine whether your product is a medical device or not. It does not determine Risk and Rules Classifications, and no risk information will appear on the final letter.
How many products can I include in a single application?	You can include up to 10 products per application. Every individual model number or unique identifier counts as one product.
Can I group or categorized types of products (like "consumable products") in one submission?	No. All products in a single application must share the exact same product name and intended use. For example, you cannot group Face Masks and Examination Gloves as under generic name "consumable products". While both are consumable PPE items, they have different names and functions.
What is screening process?	Screening is the initial check to ensure your submission is complete with the required documentation and all necessary information provided. If any information or documentation is missing, the application is returned to you. You must provide the requested details within 5 working days, or your application will be automatically withdrawn.
What is Evaluation Stage?	Evaluation is the technical review where MDA officers analyze the purpose, specifications, and function of your device to determine its final product classification.
What stages does an application go through after payment?	After your payment is cleared, the application moves into the processing

	stages, which consist of Evaluation, Verification, and Approval before the letter is issued.
When will my product classification letter be issued?	The timeline from the moment your payment is cleared and complete document submission is achieved until the final issuance of the letter is within 30 working days. This timeframe includes the evaluation, verification, and approval stages.
When will I receive my payment invoice?	Your payment invoice will be uploaded to the BayarNow system within 3 working days after your online status updates to "Payment Advice."
Can I pay by Cash or Bank Draft?	No. Cash and Bank Drafts are strictly not accepted.

Any enquiries can be sent to Medical Device Authority (MDA) at the following address:

Chief Executive
Medical Device Authority (MDA), Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC, 63000 Cyberjaya,
Selangor, MALAYSIA

Tel: +603-8230 0300

Or, please contact:

Email: classification@mda.gov.my

Contact number of the relevant officers:

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3. **Nur Farisha:** +603 8230 0356
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