



ANNOUNCEMENT

SUBJECT: UPDATE ON PRODUCT CLASSIFICATION APPLICATION SYSTEM AND IMPLEMENTATION OF VALIDITY PERIOD FOR PRODUCT CLASSIFICATION LETTER

Dear All Medical Device Industry Stakeholders,

The Medical Device Authority (MDA) extends its highest regards to all valued stakeholders.

This announcement serves to inform stakeholders that several enhancements to the [Product Classification Application System \(PCAS\)](#) will be implemented effective **1st October 2026**.

These enhancements are introduced to improve the overall application experience, streamline the product classification submission and evaluation process, enhance service efficiency, and provide a clearer and more consistent process for applicants.

1. REVISED APPLICATION FORM

The application form in the [PCAS](#) has been updated to simplify the submission process and reduce the need for manual document preparation.

Applicants are **no longer required to upload the Product Classification Template**, as the required information has been incorporated directly into the online application form.

2. IMPLEMENTATION OF NEW VALIDITY PERIOD FOR PRODUCT CLASSIFICATION LETTERS

Effective **1st October 2026**, all newly issued Product Classification Letters shall be valid for a period of **five (5) years** from the date of issuance. The validity period will be stated in the Product Classification Letter.

The introduction of a defined validity period is intended to facilitate more efficient management of Product Classification Letters, support a more streamlined renewal process, and provide greater clarity and consistency for applicants.

The implementation scope is as follows:

No.	Category	Eligibility & Criteria
1	New Product Classification Letters	Valid for five (5) years from the date of issuance.
2	Product Classification Letters previously issued with a two (2)-year validity period	- The validity period will be automatically extended to three (3) years from the original date of issuance. - No application is required for the extension.
3	Existing Product Classification Letters exceeding five (5) years	A transition period of one (1) year will be provided to allow applicants to submit a renewal application. Note: Renewal is applicable only where all information contained in the previously issued Product Classification Letter remains unchanged, including the following: - The product(s) covered under the Product Classification Letter; - The intended use; - The product description; and - The manufacturer information. Any change to the above information shall require the submission of a new Product Classification application.
4	After the transition period	- Product Classification Letters shall no longer be valid if no renewal application has been submitted within the transition period. - Applicants shall be required to submit a new Product Classification application.

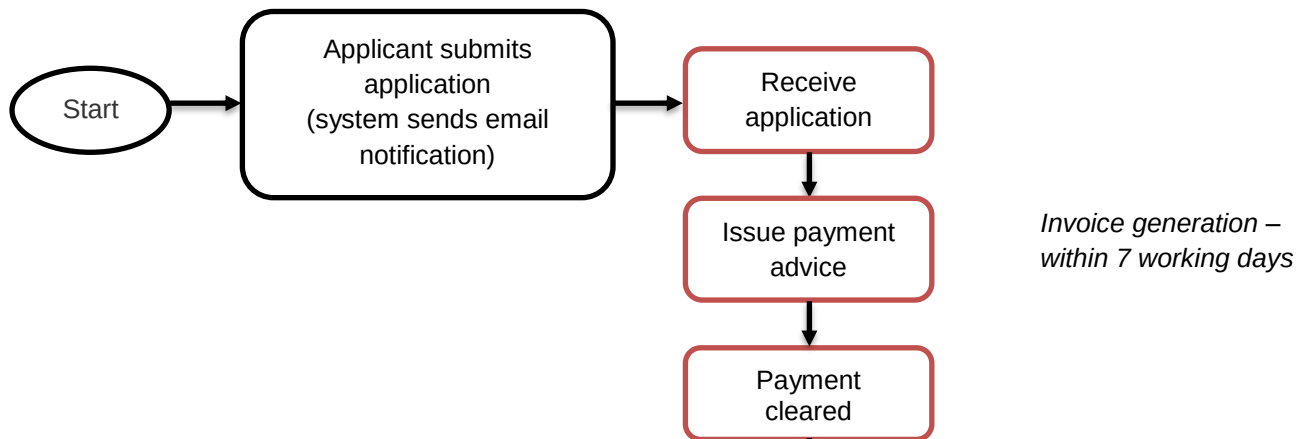
Important Note:

- i. Stakeholders are advised to review the validity status of their existing Product Classification Letters and take the necessary action within the stipulated timeline to ensure the continued validity and use of their letters.
- ii. The previous announcement on the implementation of the validity period for Product Classification Letters issued on **11 November 2025** is hereby **superseded and shall no longer apply**.

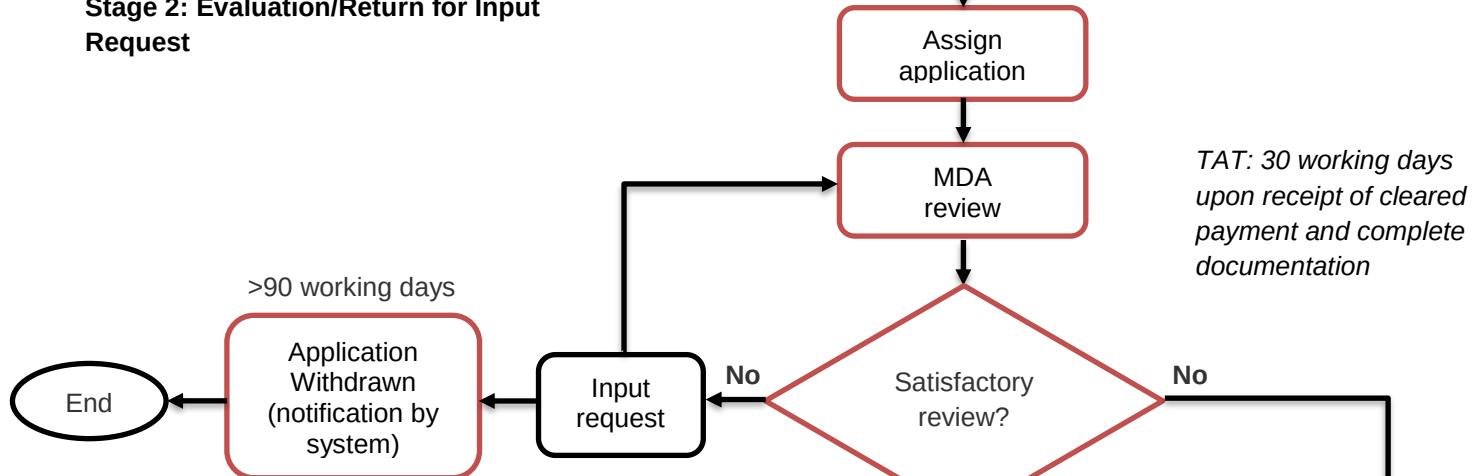
3. UPDATED APPLICATION FLOW

The application flow within the **PCAS** has been revised to facilitate a more streamlined and efficient submission and evaluation process.

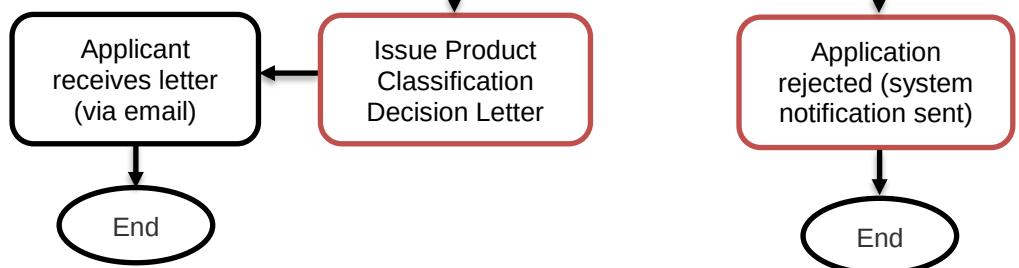
Stage 1: Payment processing



Stage 2: Evaluation/Return for Input Request



Stage 3: Complete/Reject



Process Guide

Applicant

MDA

4. WITHDRAWAL OF APPLICATION

Please be informed that Product Classification applications with no submission or response from the applicant for more than **ninety (90) working days** from the date of request for additional information will be withdrawn and shall not be further processed.

Where the required additional information, particulars, documents and/or product samples are not submitted within the specified period, the application shall be deemed withdrawn and shall not be further processed in accordance with the applicable procedure.

The withdrawal of an application does not affect the applicant's right to submit a fresh application in accordance with the prevailing requirements and procedures.

For any enquiries or assistance, please contact the Classification Unit at classification@mda.gov.my.

Thank you.

Pre-Market Control Division
Medical Device Authority (MDA)
Ministry of Health (MoH)
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Date: 30th September 2026

FREQUENTLY ASKED QUESTIONS (FAQs)

Q1: What are the key updates being implemented on 1st October 2026?

The key updates are:

- Enhancement of the Product Classification Application System (PCAS);
- Revision of the Product Classification application form;
- Implementation of a five (5)-year validity period for newly issued Product Classification Letters; and
- Withdrawal of applications with no submission or response from the applicant for more than ninety (90) working days from the date of request for additional information.

Q2: When will these updates take effect?

The updates will take effect on **1st October 2026**.

Q3: Where can I access the Product Classification Application System (PCAS)?

The Product Classification Application System (PCAS) can be accessed at <https://pc.mda.gov.my>

Q4: Is the Product Classification Template still required?

Effective 1st October 2026, applicants are no longer required to upload the Product Classification Template, as the required information has been incorporated directly into the online application form.

Q5: What is the validity period of a newly issued Product Classification Letter?

All Product Classification Letters issued on or after 1st October 2026 will be valid for **five (5) years** from the date of issuance.

Q6: How will I know the validity period of my Product Classification Letter?

The validity period will be stated in the Product Classification Letter.

Q7: What will happen to Product Classification Letters that were previously issued with a two (2)-year validity period?

The validity period of Product Classification Letters previously issued with a **two (2)-year validity period will be automatically extended to three (3) years from the original date of issuance**. No application or request is required for this extension.

Q8: What should I do if my existing Product Classification Letter has exceeded five (5) years?

A **one (1)-year transition period** will be provided to allow applicants to submit a renewal application.

Q9: What are the eligibility criteria for renewal of an existing Product Classification Letter?

Renewal is applicable only where all information contained in the previously issued Product Classification Letter remains unchanged, including:

- i. Product description;
- ii. Intended use;
- iii. Manufacturer information; and
- iv. Product(s) covered under the Product Classification Letter.

Applications involving changes to the above information shall require the submission of a new Product Classification application.

Q10: Can I add a new product to an existing Product Classification Letter during renewal?

Renewal is only applicable where all information in the previously issued Product Classification Letter remains unchanged. Any additional or new product shall require the submission of a new Product Classification application.

Q11: Can I amend the product description, intended use, or manufacturer information during renewal?

Renewal is only applicable where the information contained in the previously issued Product Classification Letter remains unchanged. Any changes to the product description, intended use, manufacturer information, or products covered will require the submission of a new Product Classification application.

Q12: Can a Product Classification Letter be renewed after it has expired?

Yes, provided that the renewal application is submitted within the applicable **one (1)-year transition period** and all renewal eligibility criteria are met. After the transition period, a new Product Classification application shall be required.

Q13: What happens if I do not submit a renewal application during the transition period?

Upon expiry of the transition period, the Product Classification Letter shall no longer be valid for use. A new Product Classification application will be required.

Q14. What is the processing timeline for a Product Classification application?

MDA will review the application within **thirty (30) working days** upon receipt of cleared payment and complete documentation.

Q15. What is the fee for a Product Classification application?

The fee for a Product Classification application is **RM300** per application.

Q16. When will the invoice be generated?

The invoice will be generated within **seven (7) working days** in accordance with the application process.

Q17. When does the thirty (30)-working-day review period begin?

The thirty (30)-working-day review period begins upon receipt of cleared payment and complete documentation by MDA. Applications with incomplete documentation or pending payment will not commence the thirty (30)-working-day review period until the required documentation is complete and payment has been cleared.

Q18. What happens if I do not respond to a request for additional information?

Product Classification applications with no submission or response from the applicant for more than ninety (90) working days from the date of request for additional information will be withdrawn and shall not be further processed.

Q19. Will the withdrawal of an application affect my ability to apply again?

The withdrawal of an application does not affect the applicant's right to submit a new application in accordance with the applicable requirements and procedures.

Q20. Does the withdrawal of an application entitle the applicant to a refund of fees paid?

Any fees paid for the withdrawn application shall not be refunded.

Q21. Does this announcement replace any previous announcement?

The previous announcement on the implementation of the validity period for Product Classification Letters issued on **11 November 2025** is superseded and shall no longer apply.

Q22. Who can I contact for further enquiries?

For further information or assistance, please contact the Classification Unit at:
classification@mda.gov.my