OFFICIAL ANNOUNCEMENT AND SUBMISSION GUIDE

SUBJECT: INTRODUCTION OF THE AUTOMATED RE-REGISTRATION ROUTE IN MeDC@St 2.0+ FOR STREAMLINED MARKET ACCESS AND CONTINUOUS SUPPLY OF MEDICAL DEVICES

Dear All Medical Device Industry Stakeholders and Registrants,

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

This announcement serves to inform the industry that the MDA is officially introducing the new **Automated Re-Registration Route** within the **MeDC@St 2.0+** platform, effective from **13th July 2026**. Re-registration applications submitted **on or after this date** will be eligible for this streamlined pathway, while applications submitted prior to this date shall continue to follow the normal evaluation route.

Please be advised that this announcement also serves as the operational user guide to provide comprehensive details on the eligibility requirements, implementation scope, and form modifications required for this new route.

USER GUIDE: AUTOMATED RE-REGISTRATION APPLICATION IN MeDC@St 2.0+

1. Introduction

The Automated Re-Registration Route in MeDC@St 2.0+ enables eligible registration holders to renew their medical device registrations through an optimized, automated submission process. This route applies to medical devices that meet all eligibility criteria specified under the Medical Device Act 2012 (Act 737), its subsidiary regulations, relevant MDA guidance documents, and the requirements outlined in this announcement.

2. Eligibility & General Requirements

Before initiating an automated re-registration application, the registration holder shall ensure strict compliance with the following criteria:

- **Licensing Status:** The establishment must hold a valid Manufacturer License or Authorized Representative (AR) License.
- **No Pending Applications:** No active Change Notification (CN) or Change of Ownership (COO) applications must exist for the device in MeDC@St 2.0+.
- **Validity Window:** The current medical device registration certificate must be active and within one (1) year prior to its expiration date.

- **Conformity Assessment:** The device must have been previously registered via either the Full Conformity Assessment or the Verification pathway, and the corresponding CAB certificate must remain valid.
- **Data Integrity:** All registration data must reflect the latest information approved by the MDA. No unapproved changes are permitted unless explicitly specified in this announcement.
- **Registration Certificate Status:** The device must not be subject to any active registration rejection, suspension, or cancellation status.

Note: This user guide must be read in conjunction with the current edition of **MDA/GD/0070** (Medical Device Registration Submission Guide for Conformity Assessment by Way of Verification Process and Submission of Application in MeDC@St).

IMPLEMENTATION SCOPE & FORM REQUIREMENTS

PART A: CLASS A MEDICAL DEVICES

The table below outlines the re-registration requirements and regulatory expectations for each section of the Class A Medical Device Registration Form. The requirements and submissions shall be read together with the current edition of MDA/GD/0070.

No.	MeDC@St 2.0+ Application Form Section Name	Re-Registration Requirement	Required Information & Supporting Documents (Ref: Annex 3 of MDA/GD/0070)
1	Medical Device Classification	Non-editable	System-generated from approved registration record.
2	Product Status Determination	Non-editable	System-generated from approved registration record.
3	Medical Device General Information	Non-editable	System-generated from approved registration record.
4	Medical Device Grouping	Non-editable	System-generated from approved registration record.
5	Additional Requirements	Non-editable	System-generated from approved registration record.
6	Manufacturer Information	Update Required	Submit a valid and current QMS certificate [(e.g., ISO 13485, MDSAP Certificate, US FDA QMSR, Japan Ministerial Ordinance No. 169, or ISO 9001 (for empty gas cylinders only)]. Note: **ONLY** the QMS certificates specified above are accepted under the automated re-registration

No.	MeDC@St 2.0+ Application Form Section Name	Re-Registration Requirement	Required Information & Supporting Documents (Ref: Annex 3 of MDA/GD/0070)
			route. Submission of any other QMS certification shall require a CN application and approval by MDA prior to re-registration.
7	Pre-Market Clearance / Approval	Update Required	Optional: Submit updated pre-market clearance or approval documentation, where available, to support the re-registration application.
8	Labelling	Update Required	Submit the latest medical device labelling reflecting the assigned MDA registration number and AR information. Note: Any other labelling changes are not permitted under the re-registration process and shall be submitted through a CN application prior to re-registration.
9	Post-Market Surveillance (PMS) & Vigilance	Update Required	Submit updated Post-Market Surveillance (PMS) and vigilance information in accordance with the requirements specified in Annex 3 of MDA/GD/0070, including the latest available PMS records covering the preceding registration period.
10	Declaration of Conformity (DoC)	Update Required	Submit an updated Declaration of Conformity (DoC).

PART B: CLASS B, C, AND D MEDICAL DEVICES

The table below outlines the re-registration requirements and regulatory expectations for each section of the Class B, C and D Medical Device Registration Form. The requirements and submissions shall be read together with the current edition of MDA/GD/0070.

No.	MeDC@St 2.0+ Application Form Section Name	Re-Registration Requirement	Required Information & Supporting Documents (Ref: Annex 4 of MDA/GD/0070)
1	Medical Device Classification	Non-editable	System-generated from approved registration record.
2	Medical Device General Information	Update Required (Certain Fields)	Updates are permitted only for registered information not captured in the form during the initial registration. Permitted fields are:

No.	MeDC@St 2.0+ Application Form Section Name	Re-Registration Requirement	Required Information & Supporting Documents (Ref: Annex 4 of MDA/GD/0070)
			• Device Meant for Export Only; • Combination Product status (must be supported by NPRA AR/EL); • Formulation for devices containing active ingredients, poisons, or drugs (e.g., creams, gels, sprays, lubricants), as registered. All other fields are non-editable.
3	Medical Device Grouping	Non-editable	System-generated from approved registration record.
4	Common Submission Dossier Template (CSDT)	Update Required (Certain Fields)	Updates shall be submitted for specific fields in alignment with Annex 4 of MDA/GD/0070, including updated Clinical Evaluation Reports (CER) / Clinical Performance Reports (CPR), latest medical device labelling reflecting the assigned MDA registration number and AR information and latest risk analysis. Note: • For **IVD cluster** grouping, update the information in Section 3 in the MeDC@St 2.0+ application form. • Any other changes are not permitted under the re-registration process and shall be submitted through a CN application prior to re-registration. All other fields are non-editable.
5	Manufacturer Information	Update Required	Submit a valid and current QMS certificate (e.g., ISO 13485, MDSAP Certificate, US FDA QMSR, Japan Ministerial Ordinance No. 169). Note: **ONLY** the QMS certificates specified above are accepted under the automated re-registration route. Submission of any other QMS certification shall require a CN application and approval by MDA prior to re-registration.
6	Pre-Market Clearance / Approval	Update Required	Optional: Submit updated pre-market clearance or approval documentation, where available, to support the re-registration application.

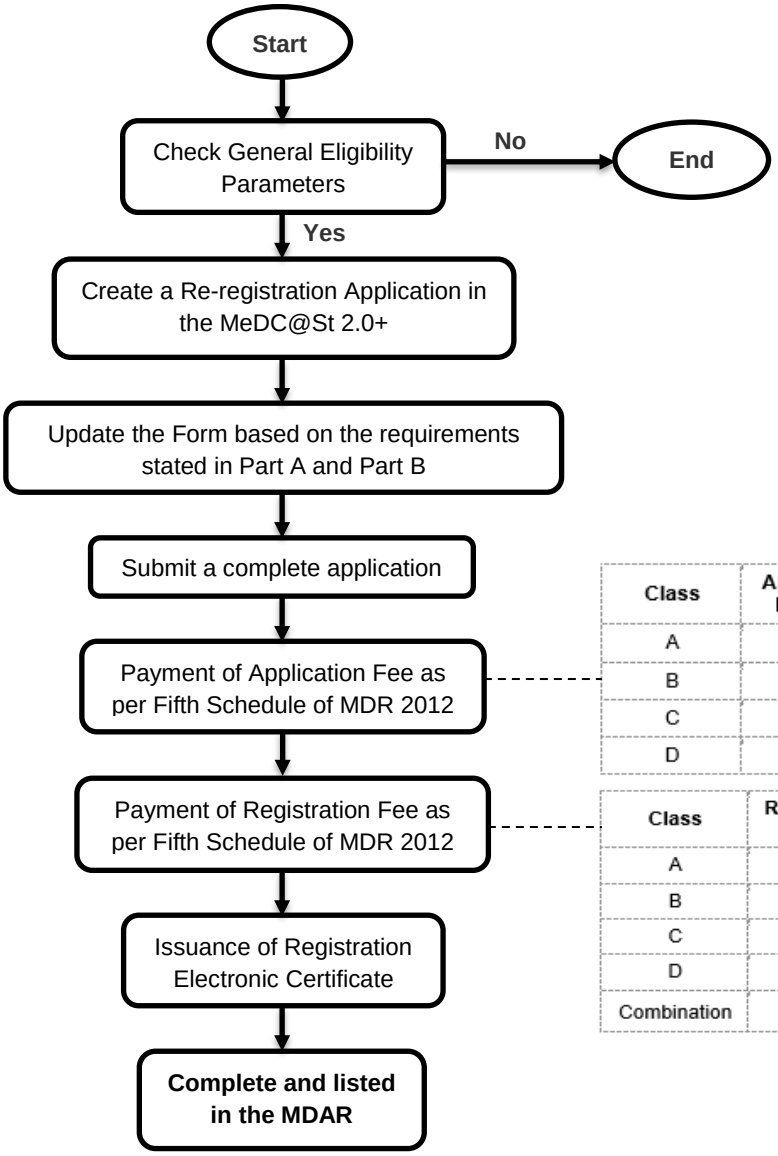
No.	MeDC@St 2.0+ Application Form Section Name	Re-Registration Requirement	Required Information & Supporting Documents (Ref: Annex 4 of MDA/GD/0070)
7	Conformity Assessment Body (CAB)	Update Required / Non-editable	**Update Required** if the current CAB certificate has expired, requiring the submission of a recertification assessment from a registered CAB. **Non-editable** if the existing CAB certificate remains valid.
8	Post-Market Surveillance (PMS) & Vigilance	Update Required	Submit updated Post-Market Surveillance (PMS) and vigilance information in accordance with the requirements specified in Annex 4 of MDA/GD/0070, including the latest available PMS records covering the preceding registration period.
9	Declaration of Conformity (DoC)	Update Required	Submit an updated Declaration of Conformity (DoC).

NOTE

- Changes/updates to registered medical device information are **prohibited** during the re-registration process unless permitted under the sections identified above or within MDA/GD/0070. Any other changes shall be approved via the CN pathway prior to initiating the automated re-registration application.
- MDA reserves the right to request additional information or conduct further regulatory review where deemed necessary.

RE-REGISTRATION FLOWCHART

The process flow below outlines the system logic execution for the Automated Re-Registration Route:



Class	Application Fee (RM)
A	500
B	250
C	500
D	750

Class	Registration Fee (RM)
A	750
B	1000
C	2000
D	3000
Combination	5000

Thank you. For further information and inquiries, please contact:

Pre-Market Control Division
Medical Device Authority (MDA)
Ministry of Health (MoH)
Level 5, Prima 9 (Block 3547)
Prima Avenue II, Persiaran APEC
63000 Cyberjaya, Selangor Darul Ehsan
Date: 10th July 2026, Revision 2

FREQUENTLY ASKED QUESTIONS (FAQs)

Q1: What is the Automated Re-Registration Route?

The Automated Re-Registration Route is a streamlined pathway within the MeDC@St 2.0+ platform that allows eligible registration holders to renew their medical device registrations automatically, without undergoing the standard evaluation route.

Q2: When does this new route take effect?

The official implementation date is **13 July 2026**. Re-registration applications submitted before this date will continue to be processed through the standard evaluation route.

Q3: What is the validity period of the registration certificate?

The medical device registration certificate is valid for a period of five (5) years.

Q4: What is the validity start date of the re-registration certificate?

The validity period will continue from the previous registration certificate.

Q5: What registration number will be assigned upon re-registration?

The registration number will remain unchanged from the previous registration certificate.

Q6: Who is eligible to use this route?

To qualify, the registration holder must meet all of the following criteria:

- Hold a valid Manufacturer Licence or Authorized Representative (AR) Licence.
- Have no active or pending Change Notification (CN) or Change of Ownership (COO) applications for the device in MeDC@St 2.0+.
- Hold a current registration certificate that is active and within one (1) year prior to its expiration date.
- The device must have been previously registered via Full Conformity Assessment or Verification.
- Hold a valid Conformity Assessment Body (CAB) certificate.
- The device registration must not be under rejection, suspension, or cancellation status.
- All information submitted must reflect the latest records approved by the MDA.

Q7: How long does the automated re-registration process take?

There is no prescribed regulatory review timeline. Processing time is dependent on the applicant successfully completing the required steps.

Q8: Can I update my medical device information during this process?

Only designated fields may be updated during the automated re-registration process, as specified in the announcement. All other submitted data must reflect the latest information approved by the MDA. Any changes outside these permitted fields must obtain prior approval through a Change Notification (CN) application before initiating the re-registration process.

Q9: What are the required fees?

Fees are prescribed under the Fifth Schedule of the Medical Device Regulations 2012 and the Medical Device Regulations (Amendment) 2025.

Device Classification	Application Fee	Registration Fee
Class A	RM 500	RM 750
Class B	RM 250	RM 1,000
Class C	RM 500	RM 2,000
Class D	RM 750	RM 3,000
Combination Product	RM 750	RM 5,000

Q10: Can I update pre-clinical reports such as biocompatibility, stability, or validation reports?

Updating technical supporting documents such as biocompatibility, stability, or validation reports is not permitted through the Automated Re-Registration Route.

If these updated reports reflect a change to the registered medical device, such changes must first be submitted and approved via the Change Notification (CN) pathway before initiating the automated re-registration process.

As stated in the announcement, any updates to registered medical device information are prohibited during re-registration unless permitted under the designated sections of the application form and MDA/GD/0070.

Q11: Is the registration holder required to maintain a valid CAB certificate after utilizing the automated route?

Registration holders are responsible for ensuring that the conformity assessment status of their medical devices remains valid throughout the validity period of the registration certificate.

During Re-Registration Submission: If the CAB certificate has expired at the time of submission, the registration holder must provide an updated recertification assessment certificate issued by a registered CAB directly into the application form. If the CAB certificate remains valid, the field will remain non-editable.

Post-Registration (MeDC@St 2.0+): Any subsequent updates to the CAB certificate and report may be submitted via the relevant Change Notification (CN) application.

Future Updates (MeDC@St 3.0): The MDA is developing functionalities that will allow CABs to upload conformity assessment certificates and reports directly into the system. Further announcements will be made once the operational procedures have been finalized.

Q12: Which existing guidance documents apply to this process?

This FAQ and the Automated Re-Registration Guide must be read in conjunction with the latest edition of MDA/GD/0070 (Medical Device Registration Submission Guide for Conformity Assessment by Way of Verification Process and Submission of Application in MeDC@St).

Q13: Who can I contact for further inquiries?

Inquiries may be directed to the Pre-Market Control Division via email: registration@mda.gov.my

Revision History

- **Initial Release:** 6th July 2026
- **Revision 1:** 10th July 2026 – Added FAQ