New ePermit System for

For Medical Device Authority ("MDA")

Internal TOT & Prelive Briefing

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Overview of MDA | Registration Module

Overview

Registration Type:

1) Super User
2) Sub User

Type of MDA Approval:

1) Registered
2) Exempted

PIA Branch:
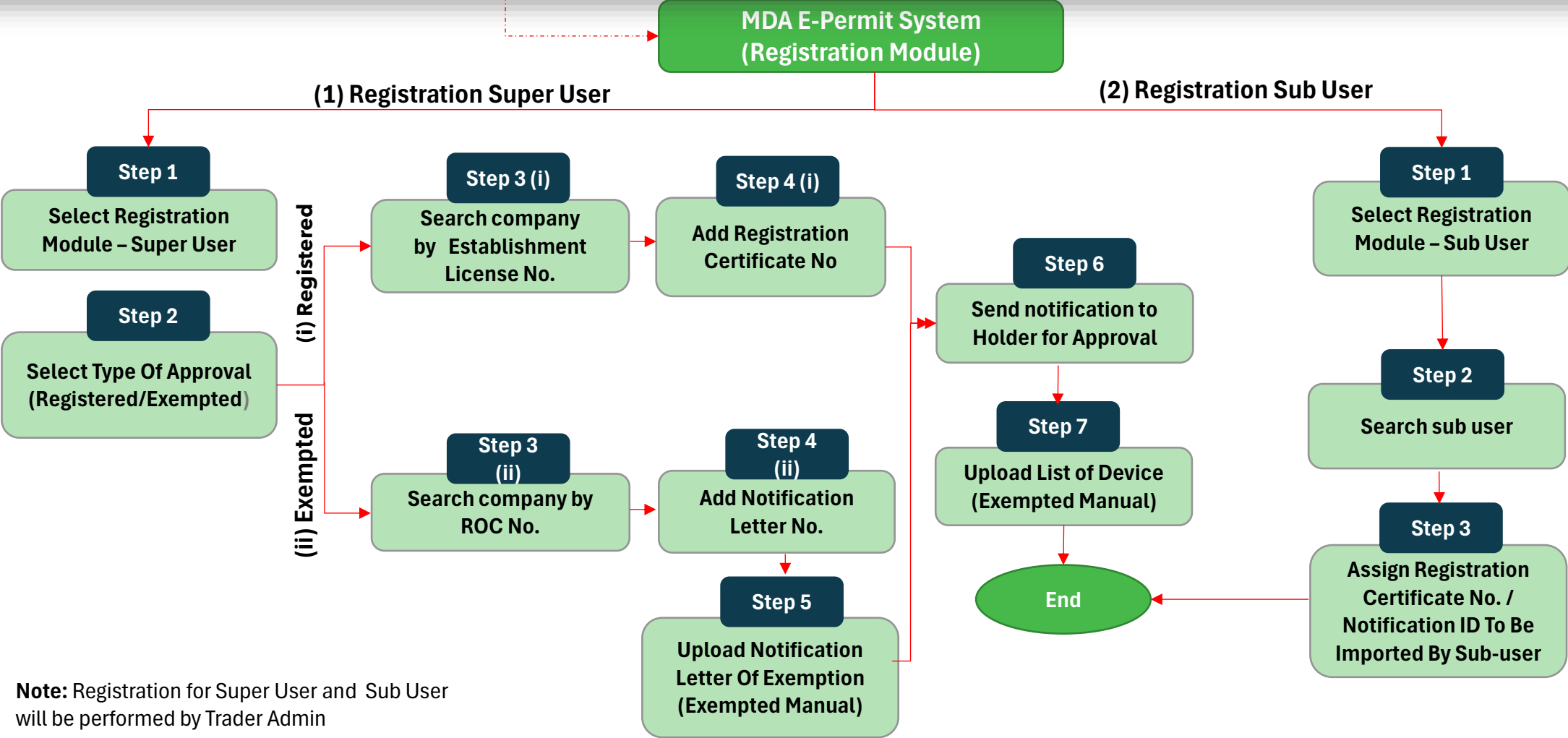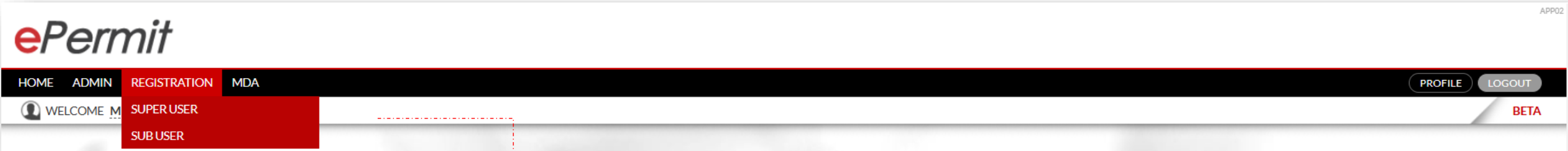**Medical Device Authority ("MDA")**

Registration Approval by:

1) Registration Certificate Holder
2) Notification Letter Holder

Type of Permit Application

1) **Import** – Registration Process is required
2) **Verification Slip (VS)** – No need to perform registration process

PROCESS FLOW: Registration Super User (Trader) and Sub User (Forwarding Agent)

ePermit

APP02

HOME | ADMIN | REGISTRATION | MDA | PROFILE | LOGOUT

SUPER USER
SUB USER

WELCOME M

BETA

MDA E-Permit System (Registration Module)

(1) Registration Super User

(2) Registration Sub User

Step 1
Select Registration Module – Super User

Step 2
Select Type Of Approval (Registered/Exempted)

(i) Registered

Step 3 (i)
Search company by Establishment License No.

Step 4 (i)
Add Registration Certificate No

(ii) Exempted

Step 3 (ii)
Search company by ROC No.

Step 4 (ii)
Add Notification Letter No.

Step 5
Upload Notification Letter Of Exemption (Exempted Manual)

Step 6
Send notification to Holder for Approval

Step 7
Upload List of Device (Exempted Manual)

End

Step 1
Select Registration Module – Sub User

Step 2
Search sub user

Step 3
Assign Registration Certificate No. / Notification ID To Be Imported By Sub-user

End

Note: Registration for Super User and Sub User will be performed by Trader Admin

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Features Highlight | Registration Module

FAQ

DAGANGNET
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Highlights

No	Area of Highlights
1	Registration Module will only be **performed by Trader Admin**
2	For the Permit application to be done by the FA, the **Sub User registration is a must**
3	**Delete the Super User** registration record: i. will **delete all the details associated to the Super User** *(ie. Registration Certificate Details, Notification ID details and Sub User)* ii. The Super User that has been deleted **is unable to perform the permit application process.** iii. In the case of a Permit application which is done by the Sub User, the **Sub User is also unable to proceed with the application** after the deletion of Super User.
4	**Untick the previously selected** Type of MDA Approval (Registered/Exempted) , will delete all the details associated to the selected type *(ie. Registration Certificate Details, Notification ID details and Sub User)*
5	**Uploaded Supporting Document** during Super User registration process is mandatory **only for 'Type Of MDA Approval = Exempted', for purpose type = manual**
6	**Upload Device List** is **only applicable for 'Type Of MDA Approval = Exempted', for purpose type = manual** , and it will only available once the status for the Notification ID = **Approved**
7	**MDA Admin:** i. Able to view the Registration details ii. Able to delete Registration Certificate No. / Notification ID added by the Super User
8	Once the **Establishment License No. / Registration Certificate has been expired**, the Super User to update the validity and details is retrieved from MDA system
9	Once the **Notification ID has been expired**, the Super User need to add new Notification ID
10	The Trader Admin is unable to update details retrieved from the MEDCAST system. For any changes required, must be made in the MDA system first

Overview of MDA | Permit Module

Overview

Permit Type:

1) Import Permit
   a) Registered
   b) Exempted (Medcast / Manual)
2) Verification Slip (VS)

PIA Processing Branch:

1) Cyberjaya (162)

PIA Branch:
Medical Device Authority (MDA)

Application & Approval:
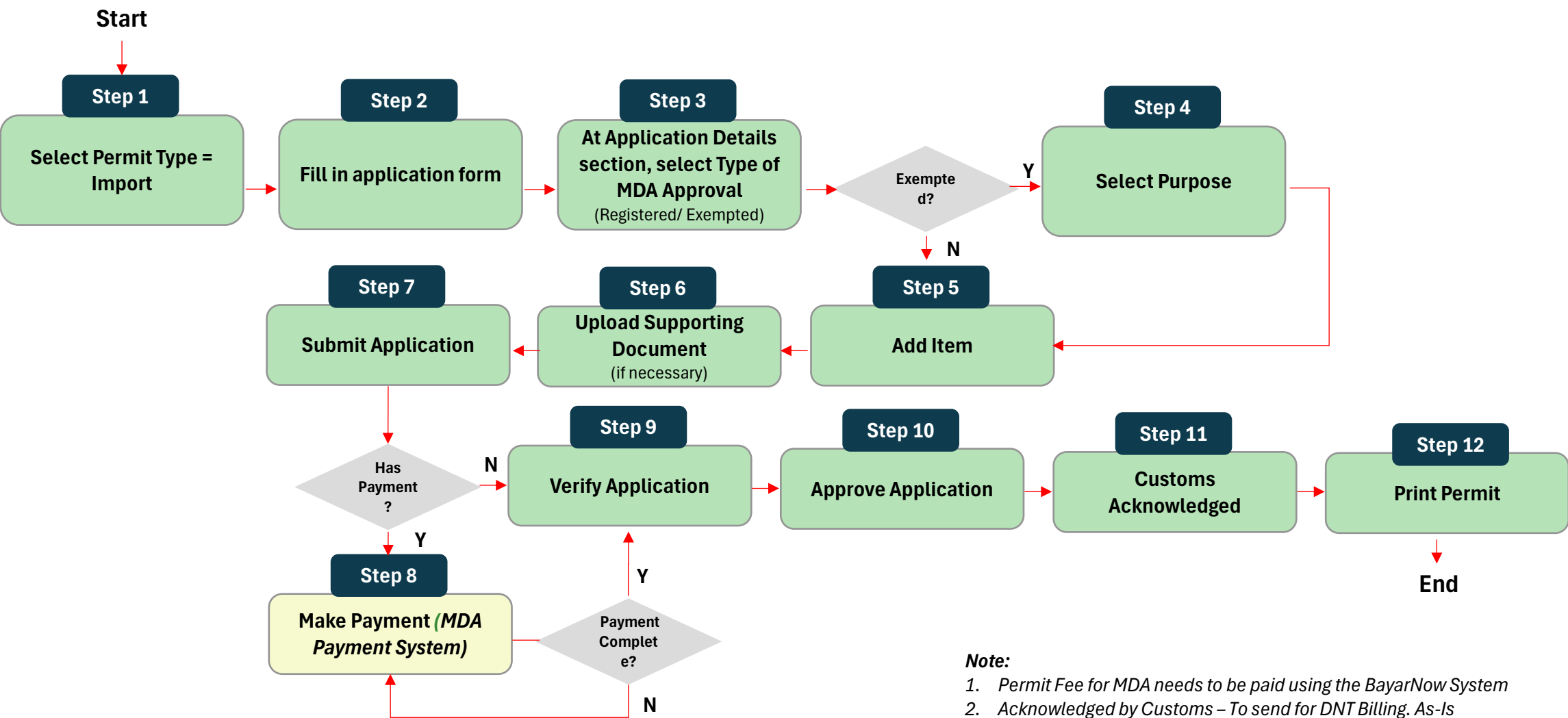
1) **Trader/FA** – Apply Import Permit/ VS
2) **Verifier (MDA) –** Verify/ Requery/Reject Import Permit Application / VS
3) **Approver (MDA) –** Approve/ Reverify/Reject Import Permit Application / VS

OGA Code: MDA

Import Permit: Send to SMK for Customs Approval (Acknowledged by Customs)
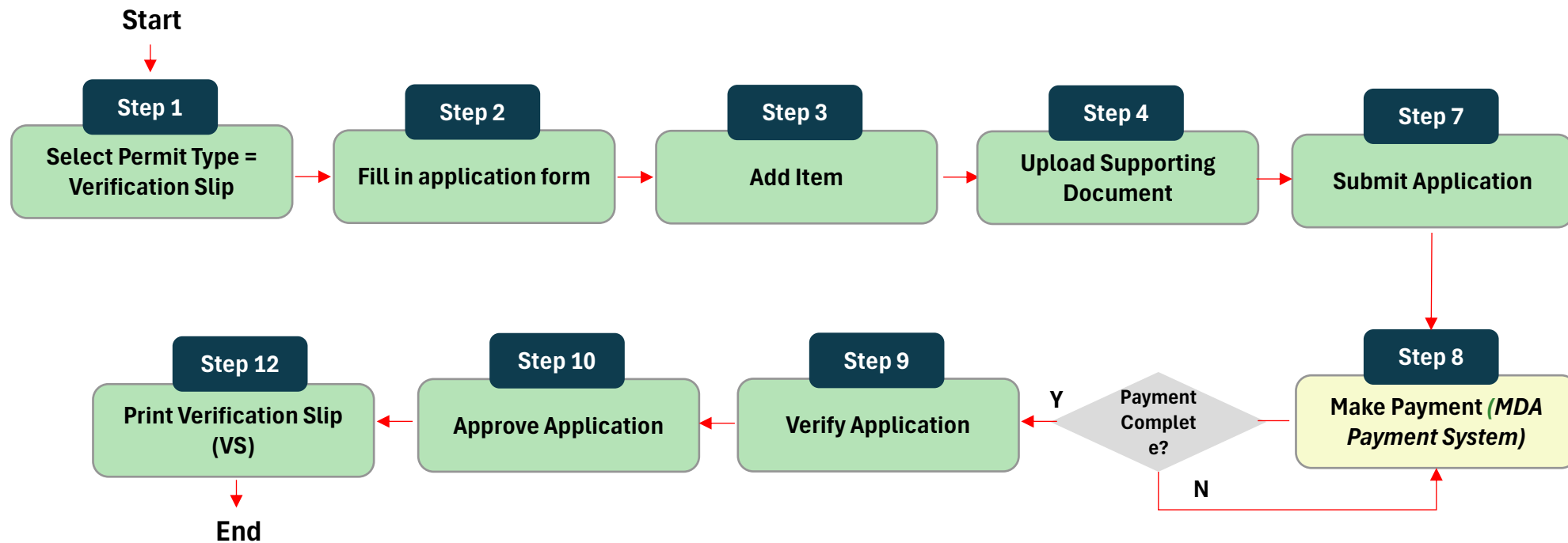
Verification Slip (VS): Approved by OGA – *process end*

PROCESS FLOW: Import Permit Application

Start

Step 1
Select Permit Type = Import

Step 2
Fill in application form

Step 3
At Application Details section, select Type of MDA Approval
(Registered/ Exempted)

Exempted? — **Y** → **Step 4** Select Purpose

N

Step 5
Add Item

Step 6
Upload Supporting Document
(if necessary)

Step 7
Submit Application

Has Payment? — **N** → **Step 9** Verify Application

Y

Step 8
Make Payment *(MDA Payment System)*

Payment Complete? — **Y** → Verify Application

N → Make Payment

Step 10
Approve Application

Step 11
Customs Acknowledged

Step 12
Print Permit

End

Note:
1. *Permit Fee for MDA needs to be paid using the BayarNow System*
2. *Acknowledged by Customs – To send for DNT Billing. As-Is Permit Charging Mechanism Applied in current ePermit system.*

PROCESS FLOW: Verification Slip Application (VS)

Start

Step 1 — Select Permit Type = Verification Slip
→ **Step 2** — Fill in application form
→ **Step 3** — Add Item
→ **Step 4** — Upload Supporting Document
→ **Step 7** — Submit Application
→ **Step 8** — Make Payment *(MDA Payment System)*
→ **Payment Complete?**
- **Y** → **Step 9** — Verify Application → **Step 10** — Approve Application → **Step 12** — Print Verification Slip (VS) → **End**
- **N** → back to Make Payment

Note:
1. *VS Fee for MDA needs to be paid using the BayarNow System*
2. *Approved by OGA– To send for DNT Billing. As-Is Permit Charging Mechanism Applied in current ePermit system.*

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Features Highlight | Permit Module

FAQ

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Highlights

No	Area of Highlights
1	**For an Import Permit application**, the Trader can only apply for the Type of MDA Approval which **has been registered in the Registration module**
2	The FA can only perform a Permit application for the assigned **Registration Certificate Number** or **Notification ID**
3	The Trader / FA unable to perform Permit application if the **Establishment License Number** has expired
4	During **Add Item** process, only valid **Registration Certificate No**. or **Notification IDs** will be displayed in the listing
5	Application can only be submitted : **i.** **Establishment License No. is** <u>not yet expired</u> **(applicable for Type of MDA Approval = Registered)** **ii.** <u>Availability</u> of Registration certificate no. / notification ID at Registration module **iii.** <u>Validity date</u> for Registration Certificate No. / Notification ID is not yet expired **iv.** <u>Availability of the device</u> **(applicable for product which been uploaded at Registration Module, for Type of MDA Approval = Exempted – Manual)** **v.** <u>Availability</u> of the VS product **vi.** **At least 1 Attachment has been provided** (<u>if there are value</u> **been entered by the Trader/FA at SAP/CIPL Identifier filed**)
6	**Permit** and **Verification Slip** Fee for MDA needs to be paid using the **BayarNow System** **(MDA Payment system)**
7	For the application with payment, the application will only available at Verifier once **payment status = Payment Completed (BayarNow)**
8	For **Application Type = Verification Slip**, the process end after the Approver approve the application
9	For **Verification Slip (VS) application,** **i.** **Application done by Trader -** the system will show and list the verification slip products uploaded by the Trader Admin **ii.** **Application done by FA -** the system will show and list the verification slip products uploaded by the FA Admin
10	No payment is required for applications that have been **queried** by the Verifier or Approver
11	If an application is **rejected** by the Verifier, Approver, or Customs, for the newly created application, the Trader / FA need to pay the application fee again