

External User Guide

Classification of a Medical Product

Table of Contents

1. Brief Overview.....	3
2. Apply for Service.....	3
2.1 Create a New Application.....	4
2.2 Product Classification Application.....	5
2.2.1 Product Details	5
2.2.2 Attachments	7
2.3 Review Application	9
2.4 Checkout.....	10
3. Take Required Actions	10
3.1 Application Correction.....	11
3.2 Sample Request.....	13
3.3 Request Appointment.....	14
3.4 Analysis Request	16
4. Rejected Applications	16
5. Printouts.....	18
5.1 Product Classification Letter	18

1. Brief Overview

This manual is prepared to navigate applicants through the Product Classification process in Emirates Drug Establishment (EDE) Portal.

This manual is designed to help applicants:

- Apply for a Product Classification service
- Manage a Product Classification application

After completing this manual, the applicant should be able to perform all activities related to Product Classification on EDE Portal.

Please note: All users can apply to this service.

2. Apply for Service

Portal users who have logged in successfully to EDE portal will be directed to Dashboard screen where they can apply to EDE's e-services. This user manual will focus on the Product Classification service.

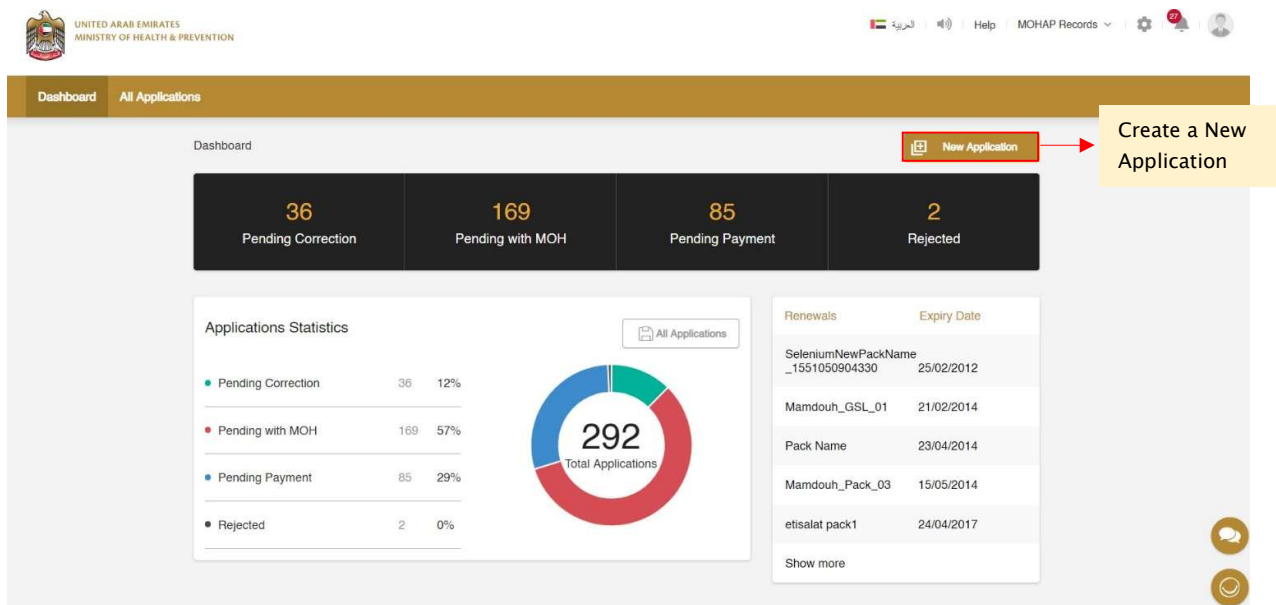


Figure A: Dashboard screen

For applicants to apply to their available services, they must go through the following process:

1. Create a new application
2. Complete application
3. Review application
4. Proceed to checkout

The sections below will help user through the step-by-step process of applying to an application.

2.1 Create a New Application

The Applicant can request to classify their products based on EDE standards by:

Requesting to create a New Application form from the Applicant Portal and selecting the following service which falls under the Product Registration services:

- Product Classification

To create a new application form from the Applicant Portal, the user must do the following:

- a. Click on one of the New Application buttons found on the Dashboard Screen (or All Applications Screen) – which opens New Application Screen
- b. Select Product Classification
- c. Click Create Application button

Once the user selects Product Classification as a service and creates an application, the user will be redirected to Product Details screen.

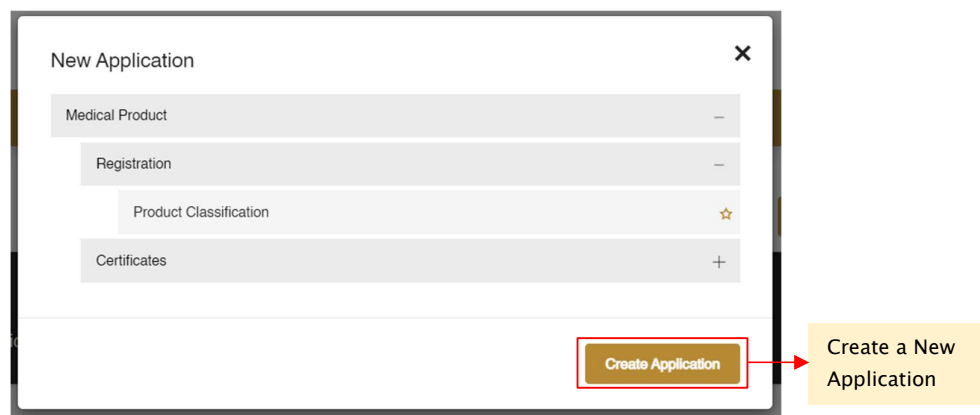


Figure B: New Application Screen

2.2 Product Classification Application

To complete a Product Classification application, the applicant must fill the following two sections:

1. Product Details
2. Attachments

For an applicant to move from one section to another, they are required to fill the section's mandatory fields and tables.



Figure C: Progress Bar

At any application stage, the applicant can perform the following actions:

- ❖ Save application
- ❖ Discard application
- ❖ Proceed to next section
- ❖ Go back to previous section

Warnings:

- In case the applicant did not complete a mandatory field, a warning message marked in red will be displayed under the field text box highlighting the note: **This Field is Required.**
- In case the applicant did not fill a table, a warning message marked in red will be displayed under the table box highlighting the note: **Table Cannot be empty.**
- In case the applicant inputs a non-numeric character in a field that only accepts numbers, a warning message marked in red will be displayed under the field text box highlighting the note: **This field accepts numbers only.**

Tips: Each application section will contain a progress bar that shows the input progress of the application data

2.2.1 Product Details

In the Product Classification – Product Details screen, the applicant must enter the following

information about the product:

Fields	Rules	Description
a. Product Name	Mandatory	Product name should be similar to the artwork (product pack/ catalogue/ country of origin issued certificate).
b. Product Form/ Dosage Form	Mandatory – If the user selects Other, they must fill in the field by text	Select suitable “Product form/ Dosage form” from the drop down list, if not available in drop down list, then select “others” and write the exact description in the pop-up box.
c. Product Description/ Indication	Mandatory	Fill the “Product Description/ Indication”.
d. List Of Accessories/ Multiple Size/ Pack Size/ Kit Components Of The Above Product In Manufacturer Letter Head Along With Manufacturer And Applicant Stamps	Mandatory	Select ‘Yes’ or ‘No’
e. List Of Accessories/ Multiple Size/ Pack Size/ Kit Components Of The Above Product In Manufacturer Letter Head Along With Manufacturer And Applicant Stamps	Conditional	Select Yes/ No in “List Of Accessories/ Multiple Size/ Pack Size/ Kit Components” field: Product Size List/ Accessories List attachment option is only applicable for product that have multiple sizes or multiple pack sizes or its own accessories, in this case select option yes and attach the document as explained below: the attachment list should show the name of the product & its sizes or name of the product & names of accessories/codes or pack sizes of the submitted product or component list of the submitted kit. the list should be in manufacturer letter head along with manufacturer and local distributor stamp, if the list is large and needs several pages, then each page has to be stamped as explained (acceptable format: PDF format with A4 page size). Any other documents eg: artwork/catalogue/product lists are not acceptable in this field, If there is no multiple sizes/ accessories for your product then select the option "NO".
f. Manufacturer	Mandatory	Fill Manufacturer Name
g. Country	Mandatory	Fill Manufacturer Country
h. City	Mandatory	Fill Manufacturer City

Table 1: Product Details Fields

Product

Product Name ⓘ
 Product name to be Classified - alphanumeric - max length 200
 This field is required

Product Form/ Dosage Form ⓘ
 This field is required

Product Description/ Indication ⓘ
 Description of the Product to be Classified - alphanumeric - max length 4000
 This field is required

List Of Accessories/ Multiple Size/ Pack Size/ Kit
 Components Of The Above Product In Manufacturer Letter
 Head Along With Manufacturer And Applicant Stamps
☐ Yes ☒ No

Manufacturer ⓘ
 Manufacturer of the Product to be Classified - alphanumeric - max length 200
 This field is required

Manufacturer Country ⓘ
 Aland Islands x

Manufacturer City ⓘ
 Country of the Product to be Classified - alphanumeric
 This field is required

Discard Attachments >

Figure D: Product Screen

Once the applicant provides the section's required information, they can move to the next section by clicking Attachments button.


2.2.2 Attachments

This section is where an applicant can upload General Attachments before proceeding to submit the application. Below are the attachments the applicant must submit before moving to the next section.










- Emirates ID Or Passport Or Trade License Or Drug Store License (Depends On The User Type) (**Required**)
- Product Picture (**Required**)
- Certificate From Country Of Origin Authority Related To The Product (CPP/Free Sale Certificate/CE/ISO) (**Required**)
- Leaflet/Product Information In English/ Arabic (**Required**)
- Outer Pack Label With Clear And Readable Product Name And Information (Artwork) (Optional)

- Inner Pack Label With Clear And Readable Product Name And Information (Artwork) (Optional)
- Composition Certificate (Active/ Inactive Ingredient List With Each Ingredient Quantity)/ MSDS (Applicable For Product That Have Medicinal/Chemical Ingredients In It) (Optional)
- Product Catalogue For Medical Devices (Optional)
- Registration And Marketing Status In Other Countries (Attach Copies Of Certificates) If Applicable (PDF And Image – Max 40MB) (Optional)

The user can add more attachments to their Product Classification application by performing the following:

1. Enter the Document Name
2. Click the Add Attachment icon 
3. Upload Attachment

Required Attachments

<p>Emirates ID Or Passport Or Trade License Or Drug Store License (Depends On The User Type) (PDF And Image - Max 40MB)</p> <p>Please attach a copy of Emirates ID or Passport or Trade License or Drug Store License (Depends on the user type) (PDF and Image - Max 40MB)</p> <p></p>	<p>Product Picture</p> <p>Please attach a copy of Product Picture</p> <p></p>
<p>Certificate From Country Of Origin Authority Related To The Product (CPP/Free Sale Certificate/CE/ISO)(PDF And Image - Max 40MB)</p> <p>Please attach a copy of Certificate from Country of Origin authority related to the product (CPP/Free Sale Certificate/CE/ISO)(PDF and Image - Max 40MB)</p> <p></p>	<p>Leaflet/Product Information In English/ Arabic (PDF And Image - Max 40MB)</p> <p>Please attach a copy of Leaflet/Product Information in English/ Arabic (PDF and Image - Max 40MB)</p> <p></p>
<p>Outer Pack Label With Clear And Readable Product Name And Information (Artwork) (Optional)</p> <p>Please attach a copy of Outer Pack Label with Clear and Readable Product Name and Information (Artwork)</p> <p></p>	<p>Inner Pack Label With Clear And Readable Product Name And Information (Artwork) (Optional)</p> <p>Please attach a copy of Inner Pack Label with Clear and Readable Product Name and Information (Artwork)</p> <p></p>
<p>Composition Certificate (Active/ Inactive Ingredient List With Each Ingredient Quantity)/ MSDS (Applicable For Product That Have Medicinal/Chemical Ingredients In It) (PDF And Image - Max 40MB) (Optional)</p> <p>Please attach a copy of Composition Certificate (Active/ Inactive ingredient list with each ingredient quantity)/ MSDS (Applicable For Product That Have Medicinal/Chemical Ingredients In It) (PDF and Image - Max 40MB)</p> <p></p>	<p>Product Catalogue For Medical Devices (PDF And Image - Max 40MB) (Optional)</p> <p>Please attach a copy of Product Catalogue for Medical Devices (PDF and Image - Max 40MB)</p> <p></p>
<p>Registration And Marketing Status In Other Countries (Attach Copies Of Certificates) If Applicable (PDF And Image - Max 40MB) (Optional)</p> <p>Please attach a copy of Registration and marketing status in other countries (Attach copies of certificates) if applicable (PDF and Image - Max 40MB)</p> <p></p>	


Document Name 

Figure E: Attachment Screen

2.3 Review Application

After the applicant completes filling all application details, they must click on the Review button to proceed with application submission. The Review section provides a full summary of the application and allows the user to perform the following actions:

- ❖ Edit Application
- ❖ Save Application
- ❖ Discard Application
- ❖ Go Back to Previous Section
- ❖ Read & Accept General Terms & Conditions
- ❖ Submit Application

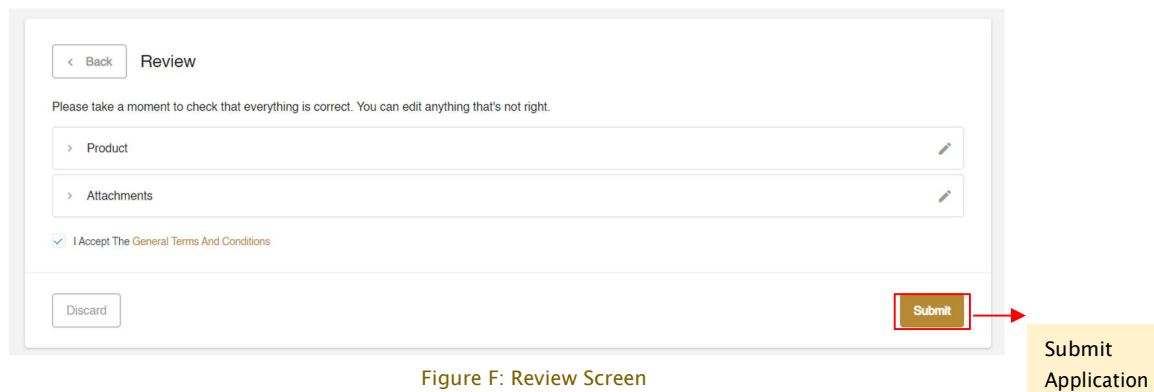




Figure F: Review Screen

Once the applicant reviews application and accepts the General Terms and Conditions, they must click the Submit button to proceed to checkout.

Please note: to proceed with application submission, the applicant must read & accept the General Terms and Conditions.

Warning: In case the user did not fill all mandatory fields, a warning message will be displayed noting that applicant must fill all required fields before submitting the application.

Display icon:

-  allows user to Edit application details
-  allows user to view table

2.4 Checkout

After an application has been submitted, the applicant will be redirected to Checkout screen where they will be asked to pay the following:

- Application Fees: AED 500 per Application

To proceed with payment, the applicant must click on the Checkout button shown at the bottom-right corner of the Checkout screen which will redirect the applicant to EDE's Payment Gateway (e-dirham).



Figure G: Checkout Screen

Tip: Overrun Pop-up Blocker to open EDE's Payment Gateway (e-dirham)

3. Take Required Actions

Once an application has been reviewed by a EDE officer, the officer might request the applicant to take actions before proceeding with application. The applicant will get notified via SMS or email once the officer requires an action.

For a user to view and take these actions, they must:

- Click on the Application Number in All Applications screen – which redirects user to Submitted Application screen
- Click on Required Actions tab
- Click on the Action – which opens an Action window

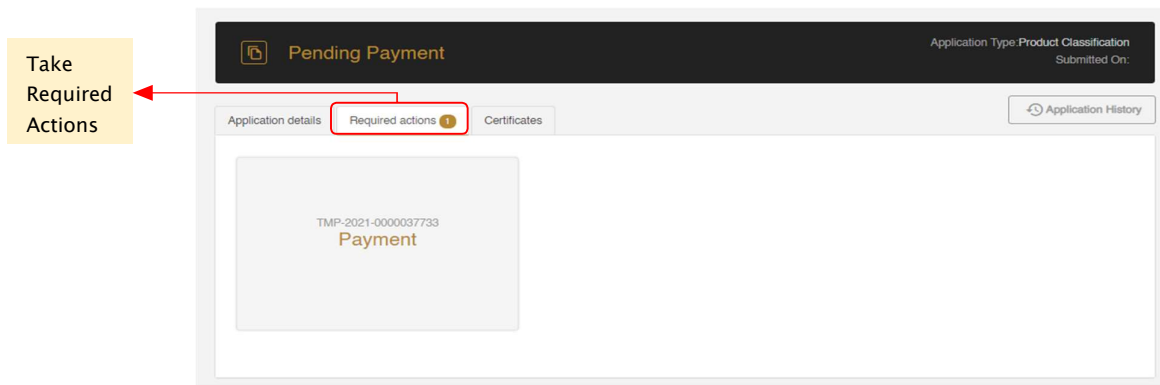


Figure H: Submitted Application Screen

The requests the officer can ask an applicant are the following:

1. Application Correction
2. Sample Request
3. Appointment Request
4. Analysis Request

These actions will be explained in detail in the following sections.

3.1 Application Correction

In case a EDE officer identifies fields/attachments in application that require modification, the officer will send back the application to applicant for correction as part of the Product Classification reviewing process.

For the applicant to view and change the fields/attachments that require correction, the applicant must:

- a. Click on Correction button found in Required Actions tab – which redirects applicant to Correction screen
- b. To view EDE Officer Comments, **please check the Remarks section or click on the Application History button.**
- b. Make changes to fields/attachments*
- c. Add comment in Comment box
- d. Click on Submit Correction button
- e. Confirm correction

Once the applicant confirms correction, the application will be sent back to officer for further review.

Rule: *Only fields/attachments needed for correction are displayed for change

Applicant can find Officer Comment under Remarks

Correction request
2021-02-18
Remarks:
test

1/2 Unresolved Request(s)

Product Details

Product

Product Name/ Trade Name
1

Product Form/ Dosage Form
Capsule

Product Description/ Indication
1

Multiple Sizes/ Accessories
☐ Yes ☒ No

Manufacturer
1

Country
Albania

Was: ~~Albania~~

City
1

Figure I: Correction Screen

Display icons:  allows the user to undo change

4/5 Unresolved Request(s)

Figure I Field Correction Tool

Country

Albania

Figure J: Modified Field

Product Form/ Dosage Form

Capsule

Figure K: Unmodified Field

Tips:

- Field Correction Tool helps user navigate from one unsolved request to another
- Fields required for change are highlighted in **Red**
- Modified fields are highlighted in **Yellow**.

3.2 Sample Request

In case a EDE officer requires an applicant to submit a sample to EDE as part of the Product Classification reviewing process, the officer will send the applicant a sample request.

This sample request will have a Sample Specification section which explains what the officer requires a sample for.

The applicant is then given the option to either:

- A. Ask for more clarification
- B. Fill & submit sample details

The screenshot displays a web form titled 'Sample Request'. At the top, there is a navigation bar with a '< Back' button and the text 'Analysis'. Below this, the form has a header section with 'Sample Request', the date '06-01-2019', and an 'Officer Comment' field. The main body of the form is titled 'Sample Details' and contains three input fields: 'Courier Company Name', 'Tracking Number', and 'Send Date'. Each of these fields has a red error message 'This field is required' displayed below it. At the bottom of the form, there are two buttons: 'Ask For Clarification' and 'Submit'.

Figure L: Sample Request Screen

Case A

In case the applicant requires more clarification before proceeding to fulfill sample request, the user must do the following:

- a. Click on Request Sample button found in Required Actions tab – which redirects applicant to Request Sample screen
- b. Click Ask For Clarification button – open a Clarification window
- c. Fill Clarification box
- d. Click Ask For Clarification button

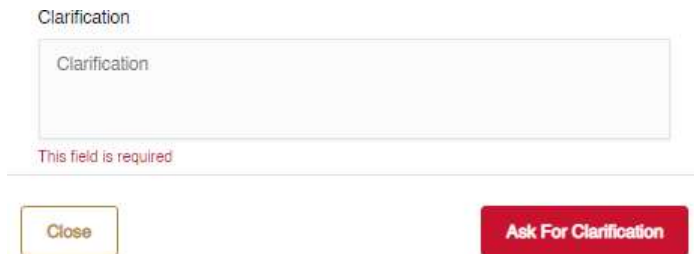
A screenshot of a 'Clarification' window. It features a text input field with the placeholder text 'Clarification'. Below the field, a red error message states 'This field is required'. At the bottom of the window, there are two buttons: a yellow 'Close' button on the left and a red 'Ask For Clarification' button on the right.

Figure M: Clarification Window

Case B

For the applicant to provide sample details to EDE, they must:

- a. Click on Request Sample button found in Required Actions tab – which redirects applicant to Request Sample screen
- b. Fill the following information in Sample Details section:
 - Courier Company Name
 - Tracking Number
 - Send Date
- c. Click Submit button
- d. Confirm Sample Receipt

Once the applicant confirms, the sample details will be sent back to officer for further review.

3.3 Request Appointment

In case a EDE officer requires to have an appointment with applicant as part of the Product Classification process, the officer will send the applicant an appointment request.

This appointment request includes the following:

- Appointment Date
- Appointment Time
- Appointment Location

The applicant is given the option to either

- A. Accept this appointment
- B. Suggest a New Appointment

Case A

For the applicant to accept an appointment, they must:

- a. Click on Request Appointment button found in Required Actions tab – which redirects applicant to Appointment screen
- b. Review appointment details
- c. Click on Accept button
- d. Confirm appointment

The screenshot displays an 'Appointment request' interface. At the top, it shows the date '28-01-2019' and a 'Remarks' section with the text 'remarks of appointment:'. Below this, the 'Appointment Date' is '09-02-2019', the 'Time' is '11:23 AM GMT+04:00', and the 'Location' is 'Ministry of Health – Drug Registration Department'. At the bottom of the screen, there are two buttons: 'Suggest New Appointment' on the left and 'Accept' on the right.

Figure N: Appointment Screen

Case B

In case an applicant wishes to suggest an appointment, they must:

- a. Click on Request Appointment button found in Required Actions tab – which redirects applicant to Appointment screen
- b. Click on Suggest New Appointment button – which opens New Appointment window
- c. Fill the following in New Appointment window:
 - Appointment Date
 - Time (Optional)
 - Leave a Comment (Optional)
- d. Click Submit button

Once the applicant submits suggested new appointment, the new appointment form will be sent back to officer for further review.

Figure O: New Appointment Window

3.4 Analysis Request

As part of the Product Classification reviewing process, a EDE officer might request for an Analysis on a medical product.

For this request to be initiated, the applicant must first pay the following fees:

- Analysis fees: AED 3000
- Certificate fees: AED 500

During the Analysis evaluation, the Analysis officer can request the applicant the following:

1. Application Correction – [Section 3.1](#)
2. Sample – [Section 3.2](#)
3. Appointment – [Section 3.3](#)

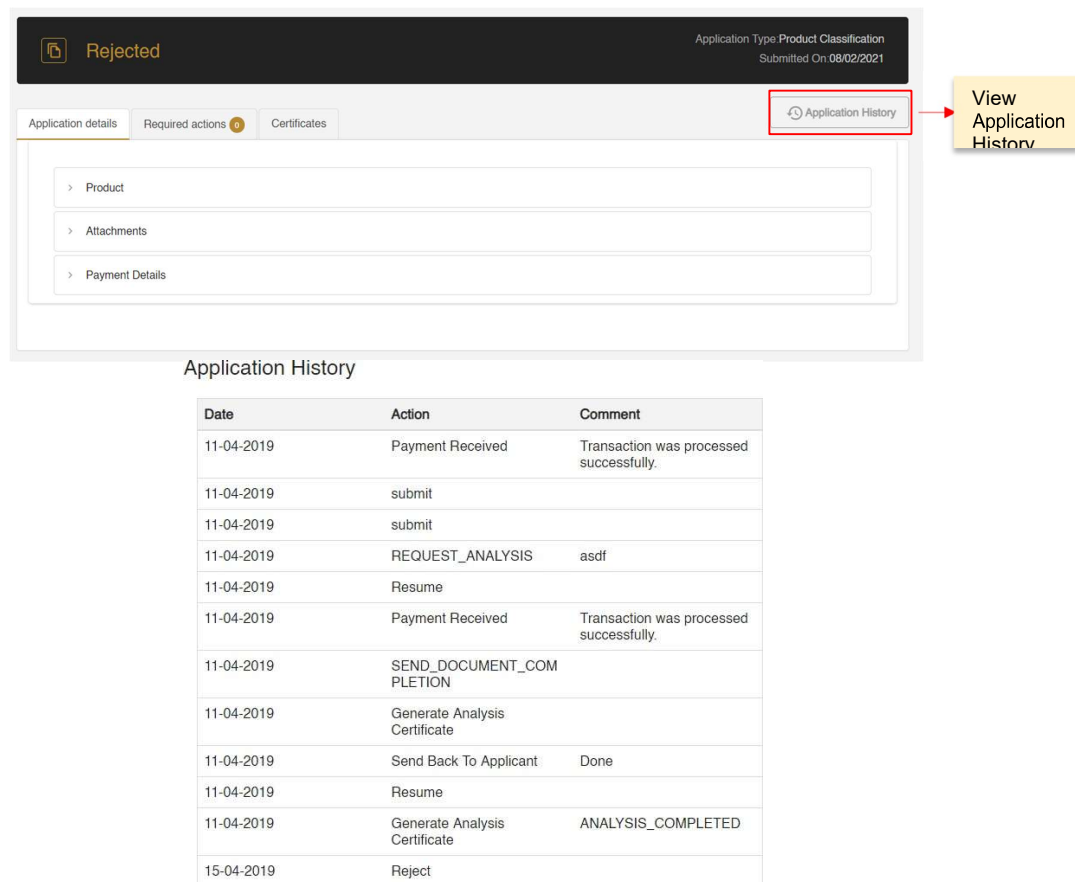
Tip: To learn how to fulfill the requests above, please refer to their respective sections

4. Rejected Applications

Once an application has been rejected by a EDE Officer, an email or an SMS will be sent to

the applicant containing the application's latest updates and results.

To view the rejection comments given by EDE Officer and the step at which the application got rejected, please click on the Application History button.



Rejected Application Type Product Classification Submitted On 08/02/2021

Application details Required actions Certificates Application History

> Product

> Attachments

> Payment Details

Application History

Date	Action	Comment
11-04-2019	Payment Received	Transaction was processed successfully.
11-04-2019	submit	
11-04-2019	submit	
11-04-2019	REQUEST_ANALYSIS	asdf
11-04-2019	Resume	
11-04-2019	Payment Received	Transaction was processed successfully.
11-04-2019	SEND_DOCUMENT_COMPLETION	
11-04-2019	Generate Analysis Certificate	
11-04-2019	Send Back To Applicant	Done
11-04-2019	Resume	
11-04-2019	Generate Analysis Certificate	ANALYSIS_COMPLETED
15-04-2019	Reject	

Figure Q: Application History

5. Printouts

Once an application has been reviewed and approved by a EDE officer, the officer will issue the applicant a Product Classification Certificate. The applicant will instantly get notified via SMS or email once the officer issues the certificate.

For a user to view and printout a certificate, they must:

- Click on the Application Number in All Applications screen – which redirects user to Submitted Application screen
- Click on the Certificate tab
- Click on the Attachment – which opens the certificate as a PDF
- Print PDF

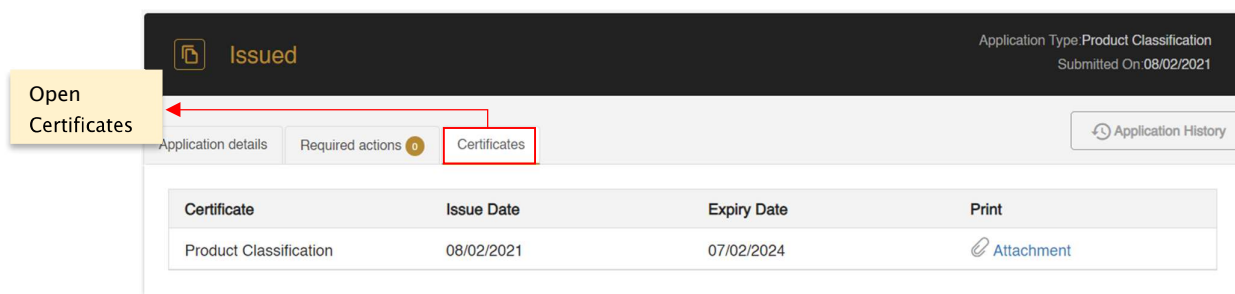


Figure R: Submitted Application Screen – Printout

5.1 Product Classification Letter

The Product Classification Letter will contain the following information:

- Application No
- Issue Date
- Expiry Date
- Applicant Name, City, Country
- Committee M. No. , Dated
- Product Name & Form
- Manufacturer Name & Country
- Classified As