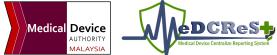
USER MANUAL FRONT END USER

MEDICAL DEVICE CENTRALIZED REPORTING SYSTEM (MeDCReSt)

DISEDIAKAN OLEH :



Version 1.0

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1 INTRODUCTION

This user manual is prepared for the purpose of the operational function of the Post Market Online Reporting System.

Medical Device Centralized Reporting System (MeDCReSt) is developed using a web-based method in which it utilises the internet access via internet server. In order to access this system, user has to key in the URL address onto the internet server as followed:

https://medcrest.mda.gov.my

The screen below shows the expected webpage after the address has been keyed In.

Login Utername Password Remember Ma Rememb	MEDICA	AL DEVICE CENTRALIZED REPO	RTING SYST
Password Rumamber Ma Ruma Market Ma Ruma Market		Login	
Rumamber Ma Regain Tour Password? ** Attention ** Attention ** Attention ** Attention allow, If assess the limit the assesser will ked. for 2 remains	Username		
Sign in Forgot Your Password? ** Attention ** . 1: Only 3 strength allow, If account the limit the account will look for 2 minutes	Password		8
** Attaction ** 1. Only 3 attacture allow, if account the invest the account will include for 2 monutes		C Remember Me	
 Only 2 attempts allow, If account the limit the account will look for 2 minutes 			
		1. Only 3 attangs alow, if acoust the limit the account will	
Guidance FM4 User Mental Future View Frequeer	Guidance FAQ	User Manual Public View	Helpdook
Documenta	Documents	Eading	

The user manual contains important information on operating the online reporting system, correctly and efficiently. Following this user manual helps establishments to carry out responsibilities of post market requirements under Medical Device Act 2012, Act 737, Medical Device (Duties and Obligation of Establishments) Regulation 2019 and its respective guidance documents conveniently, quick and easy as possible.

2 GENERAL

2.1 LOGIN

Login	er Username			
	Username	apps	2	Enter Password
Click "Sign In	button 3	Remember Me Forgot Your P Attention ** 73 attempts allow, If esceed the mates		
Guidance Documents	FAQ	User Manual	Public View Listing	Helpdesk

- a. The Login page will be displayed as above and the user required to fill the information needed (*Please use your MeDC@St 2.0+ log in information (Main Account) for the first-time user*.):
 - 1. Please enter the User username.
 - 2. Please enter the User password.
 - 3. Click the sign In button.
 - 4. The pop-up below will be displayed:

Confirmation × Is the device registered with MDA are available in Malaysian market? Yes No		
	Confirmation	×
Yes No	Is the device registered with MDA are available in Malaysian market?	
	Yes No	

5. If the device registered with MDA are available in Malaysian market

click button and the system will redirect the user to the Dashboard (Refer to 2.3 DASHBOARD).

6. If the device registered with MDA are not available in Malaysian

market click button and the pop-up instruction for manual reporting will be displayed as below.

Please fill in the related form that is available from the links, If you are reporting an Incident, select MPR, If you are reporting a Field Corrective Action, select FCA, and if you are reporting a Medical Device Recall, select Recall :- → Mandatory Problem Reporting → Field Corrective Action 2	If you are reporting an Incident, select MPR, If you are reporting a Field Corrective Action, select FCA, and If you are reporting a Medical Device Recall, select Recall :- 	Confirmation	×
If you are reporting a Field Corrective Action, select FCA, and If you are reporting a Medical Device Recall, select Recall :- → Mandatory Problem Reporting	If you are reporting a Field Corrective Action, select FCA, and if you are reporting a Medical Device Recall, select Recall :- → Mandatory Problem Reporting Field Corrective Action Recall		
Mandatory Problem Reporting	→ Mandatory Problem Reporting → Field Corrective Action 2 → Recall 3	If you are reporting a Field Corrective Action, select FCA,	
	→ Recall 3	Mandatory Problem Reporting	

- I. If the user wants to make a report of an Incident, please click the **"Mandatory Problem Reporting**" link.
- II. If the user wants to make a report of Field Corrective Action, please click the "Field Corrective Action" link.
- III. If the user wants to make a report of Recall, please click the "Recall" link.
- IV. If the user wants to cancel, please click the button.
- b. The user needs to log in to the system using the same username and password as the MeDC@St 2.0+ account.
- c. If the user wants to reset their password, please click the "Forgot Your Password ?" button.
- d. If the user wants to view the FAQ, please click the "FAQ" button.
- e. If the user wants to view the User Manual, please click the "User Manual" button.
- f. If the user wants to view the Public View Listing, please click the "**Public View Listing**" button.
- g. If the user wants to view the Helpdesk, please click the "**Helpdesk**" button.

2.2 LOGOUT

		CI	ick " Profile	" icon	1	
	0	Search			0	
a. The but		on button is locate ne system will dis			ar. Click the	icon
		HOST 011				
		Account		ick " Logo	ut " button	
			-			

- b. Click ⁽¹⁾ Logout button.
- c. The system will end the user session and will redirect the user to the login page.

2.3 FORGET PASSWORD

- a. The Forget password page will be displayed as above and the user required to fill the information needed:
 - 1. Please enter the User username.
 - 2. Click the system will send an email.
- b. The user will received an email as below:

Hello!
You are receiving this email because we received a password reset request for your account.
Click "Reset Password" button
This password reset link will expire in 60 minutes.
If you did not request a password reset, no further action is required.
Thank You, Sincerely, Post Market Surveillance & Vigilance (PMSV)
If you're having trouble clicking the "Reset Password" button, kindly click on the un given <u>bitss://dev.cmsv.mda.gov.my/dev/pmsv/public/password/isset/effebed</u> Zad26602e4f5e1da0d12ee50a5c3f2f35bd8e1564c64a81f19a6ee80f67email-muha mmadzahfti40mda.gov.mv 2 Copy "Link" Given

1. To continue with reset password, User need to click the

Docot	Password
Reset	Password

button or copy the "Link" given in the email.

c. After click the system will displayed as below to proceed for the next step:

Notes Please do not enter the same password as previous Your password should contain the Following: Atleast 1 Uppercase letters (A-2) Atleast 1 Lowercase letters (a-2) Atleast 1 Lowercase letters (a-2) Atleast 1 special character (a.g. '98#\$X^&*0+') Enter Username Username Username Username Confirm Password Confirm Password	Reset Password	
New Password Enter New Password Enter Confirm Password	Please do not enter the sam Your password should conta Atleast 1 Uppercase letters (Atleast 1 Lowercase letters (Atleast 1 Number (0-9) Atleast 1 special character (Enter Username	ain the Following: (A-Z) (a-z) (a.g. '\@#\$%^&*()_+')
Coopling Decouverd	New Password	
	Confirm Password	

- 1. Please enter the username.
- 2. Please enter the new password.
- 3. Please enter the confirm password.
- 4. Click the Reset Password button. If the reset password is successful the system will redirect the user to the Dashboard (Refer to 2.3 DASHBOARD).

2.4 DASHBOARD

	 KP-HOSTOH HOST OH 		y Development			
				0	Search	٩
2	No	Name	Username		Role	
ist of Users	1 Showing 1 of 1 entries.	HOST 0H	host011@test		Superuser	
MPR Reg	orting Form	FCA B	eporting Form	Rec	all Reporting Form	n.
Current	Completed	Current	Completed	Current		npleted
47	0	17	1	23		0
	m is : 88 st of MPR		port Counter	0	Latest of Recall	
Late	at of MPR	5 Latest of	nest of FCA	6 Latest of	fRecall	Action
Latest of I	st of MPR	5 Latest of Type Of Report	riest of FCA			Action
Latest of Latest of 1 MDM/	et of MPR MPR Reference No.	5 Latest of	nest of FCA	Latest of Date (dd/mm/yy)	f Recall Status	@ View
Latest of Ke. 1 MDA/1 2 MDA/1	at of MPR MPR Reference No. MPR/P03%6-73777966-2022	5 Latest of Type Of Report Reporting	nest of FCA	Latest of Date (dd/mm/yy) 24/03/2022	f Recall Status Draft	@ View
Latest of Ke. 1 MDA/1 2 MDA/1 3 MDA/1	et of MPR MPR Reference No. MPR/P0316-73777966-2022 MPR/P0316-56666970-2022	5 La Latest of Type Of Report Reporting Reporting	rtest of FCA FCA Medical Device Name	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022	FRecall Status Druft Druft	 Wiew Wiew Wiew
Latest of Ke. 1 MDA/1 2 MDA/1 3 MDA/1 4 MDA/1	at of MPR MPR Reference No. MPR/P0316-56866970-2022 MPR/P0316-56866970-2022	5 La Latest of Type Of Report Reporting Reporting Reporting	rtest of FCA FCA Medical Device Name	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022 17/03/2022	f Recall Status Draft Draft Submitted	View View View View View
Latest of Latest of Mo. 1 MDA/1 2 MDA/1 3 MDA/1 6 MDA/	est of MPR MPR Reference No. MPR/P0316-73777966-2022 MPR/P0316-568669970-2022 MPR/P0314-69244698-2022 MPR/P0312-67933226-2022	5 La Latest of Type Of Report Reporting Reporting Reporting Reporting	Medical Device Name	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022 17/03/2022 16/03/2022	FRecall Status Draft Draft Submitted	View O View O View O View O View O View
Latest of Kex 1 MDA/1 2 MDA/1 3 MDA/1 4 MDA/1 6 MDA/1	Alt of MPR MPR Reference No. MPR/P0315-56866970-2022 MPR/P0315-56866970-2022 MPR/P0315-56986970-2022 MPR/P0315-56986970-2022 MPR/P0315-56986970-2022	5 Latest of Type Of Report Reporting Reporting Reporting Reporting	Medical Device Name	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022 15/03/2022 16/03/2022 17/03/2022	FRecall Status Draft Draft Submitted Submitted	Action @ View @ View @ View @ View @ View @ View @ View
Latest of Latest of MDA/1 2 MDA/1 3 MDA/1 4 MDA/2 5 MDA/2 7 MDA/2	at of MPR MPR Reference No. MPR/P0316-73777966-2022 MPR/P0316-56866970-2022 MPR/P0314-568244598-2022 MPR/P0314-568244598-2022 MPR/P0314-9450907-2022 MPR/P0314-9450907-2022	5 La Latest of Type Of Report Reporting Reporting Reporting Reporting Reporting Reporting	MEDICAL TESTONIB	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022 17/03/2022 16/03/2022 16/03/2022 16/03/2022	Recall Status Draft Draft Submitted Submitted Submitted	View View View View View View View View
Latest of Latest of 1 MDA/1 2 MDA/1 3 MDA/1 4 MDA/1 6 MDA/1 7 MDA/1 8 MDA/1	At of MPR Reference No. MPR/P0356-73777966-2022 MPR/P0356-56866970-2022 MPR/P0354-69244598-2022 MPR/P0354-69244598-2022 MPR/P0354-69244598-2022 MPR/P0354-69244598-2022 MPR/P0354-6944598-2022	Latest of Type Of Report Reporting Reporting Reporting Reporting Reporting Reporting Reporting Reporting Reporting	MEDICAL TESTONIB	Latest of Date (dd/mm/yy) 24/03/2022 24/03/2022 16/03/2022 16/03/2022 16/03/2022 16/03/2022 22/03/2022	FRecall Status Draft Draft Submitted Submitted Submitted Submitted	 View View View View View View View View

- a. The Dashboard page will be displayed as above:
 - 1. Establishment Details (Refer to 2.3.1 Establishment Details).
 - 2. Table list of Users (Refer to 2.3.2 Table list of Users).
 - 3. Report Counter (Refer to 2.3.3 Report Counter).
 - 4. Latest of MPR (Refer to 2.3.4 Latest of MPR).
 - 5. Latest of FCA (Refer to 2.3.5 Latest of FCA).
 - 6. Latest of Recall (Refer to 2.3.6 Latest of Recall).

2.4.1 Establishment Details



- a. This section will display establishment details that consist of:
 - 1. Establishment Name
 - 2. Establishment Licence Number
 - 3. Person Responsible Name

2.4.2 Table list of Users

			Table Filtering	1
	No	Name	Username	Role
(1	ICT Development Team	host010@test	Superuser
	2	Ainul Mardiah	ainul@dev	Subuser
• • • • • •	3	Zahroh	drafter	Subuser
User	4	Aiman Syafiq	aiman@devTeam	Subuser
Information	6	Aazannie Firdaus	aszario	Drafter
	Showing 5 of	7 entries.		
			Page Navigation	_

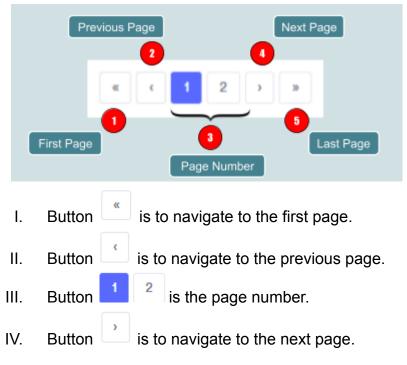
- a. This section will display list of user :
 - 1. Table Filtering

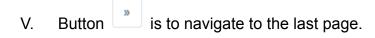


I. User can click (1) icon and the pop-up information related to table filtering will display as below:

Searching Steps		
1. Type any keyword:		
 Name 		
 Username 		
 Role 		
2. Click the search icon	button (Q) to find the report.	
		_
	Click "Close" button 2	Close

- II. Enter any related keyword (based on information given).
- III. Click icon and the system will display the result.
- 2. User Information that consist of:
 - I. Name
 - II. Username
 - III. Role
- 3. Page Navigation





2.4.3 Report Counter

- a. Dashboard have three (3) report counter that will be displayed as above:
 - 1. **MPR Reporting Form** This counter displays the number of Current MPR reports that are in process and MPR reports that are Completed.
 - 2. **FCA Reporting Form** This counter displays the number of Current FCA reports that are in process and reports FCA that are Completed.
 - Recall Reporting Form This counter displays the number of Current Recall reports that are in process and Recall reports that are Completed.
 - 4. **Total Application Form** This counter displays the total number of reports that are in process and reports that are completed for all modules (MPR, FCA, Recall).

2.4.4 Latest of MPR

	Latest of MPR	L	itest of FCA		Latest of Recall	
				Clic	k "View" bu	tton
No	Reference No.	Type Of Report	Medical Device Name	Date (dd/mm/yy)	Status 2	Actio
1	MDA/MPR/P0259-96870941-2022	Reporting	MEDICAL TESTOIOD	17/02/2022	Draft	(ii) Ve
- 2	MDA/MPR/P0234-21738103-2022	Reporting	MEDICAL TESTORIO	03/03/2022	Draft	(B) Ve
- 1	MDA/MPR/P0223-35978696-2022	Reporting	MEDICAL TESTORIO	29/09/2022	Submitted	(B) Vie
- 4	MDA/MPR/P0222-61153156-2022	Reporting	MEDICAL TESTORIO	21/01/2022	Submitted	(B) Ver
J٠	MDA/MPR/P0225-07320789-2022	Reporting	MEDICAL TESTORIA	21/01/2022	Submitted	(B) Ver
١	MDA/MPR/P0220-6400H75-2022	Reporting	MEDICAL TESTORIA	21/01/2022	Submitted	(B) Ve
7	MDA/MPR/F0299-37999934-2022	Reporting	MEDICAL TESTOIDC	21/01/2022	Submitted	(B) Ve
	MCA/MPR/P0248-26822882-2022	Reporting	MEDICAL TESTOIOB	21/01/2022	Submitted	(i) Ve
	MDA/MPR/P0217-92944355-2022	Reporting	MEDICAL TESTOIOD	21/01/2022	Submitted	(i) Ve
	MDA/MPR/P0216-675679/78-2022	Reporting	MEDICAL TESTOIDC	21/01/2022	Submitted	@ Vie

- a. Latest of MPR will be displayed as above:
 - 1. List of Report This table will display ten (10) latest reports of MPR.
 - Click View button and the system will display the report. (Refer to 3.5 VIEW).

2.4.5 Latest of FCA

		Labort of MPR		Latest of FCA		Later	t of Recall	
		Balarance no.	Medical Device Name	Date Submission (dd/mm/yy)	Date to be Completed (dd/mm/yy)	Type of Report	Bata	lick "View"
	1	MDA/FCA/PXD830- 34542823-2022	MEDICAL TEST0400		24/02/2022	Notification	Overdue	2 10 View
	2	MDA/TCA/990329- 22800630-2022	MEDICAL TESTOIOB		20/02/2022	Notification	Overdue	(B) View
	x	MDA/FCA/990380- 444089/2-2022	MEDICAL TESTOIDA		20/02/2022	Notification	Overdue	di View
	4	MDA/TCA/7X0306- 70647983-2022	MEDICAL TESTORO		20/02/2022	Notification	Overfax	(B) View
▶ {	5	MDA/FCA/PX0306- 62076107-2022	MEDICAL TESTOIDA		20/02/2022	Notification	Overdue	(B) View
t of port	6	MDA/TCA/PX0306- 54260762-2022	MEDICAL TESTDIDC		20/02/2022	Notification	Overfox	@ View
	7	MDA/FCA/PX5304- 72835875-2022	MEDICAL TESTOIOB		20/02/2022	Notification	Overdue	(B) View
	8	MDA/TCA/FXD802- 4095/829-2022	MEDICAL TESTINIDO		50/05/2022	Notification	Overdue	(B) View
	-	MDA/FCA/FH0299-7642523- 2022	MEDICAL TESTIMO		20/02/2022	Notification	Overdue	(B) View

- a. Latest of FCA will be displayed as above:
 - 1. List of Report This table will display ten (10) latest reports of FCA.
 - 2. Click View button and the system will display the report. (Refer to 4.4 VIEW REPORTING)

2.4.6 Latest of Recall

	Latest of MPR		Latest of FCA		Latent	rf Recall	
							Click "View" but
84	Recall Reference no.	Medical Device Norne	Date of Reporting (dd/mm/yy)	Due Date (dd/term/yy)	Reporting Stage	Status	Action 2
1	MDA/Recall/P0263-72747738- 2022	MEDICAL TESTORC	31/03/2022		Notification	Draft	CO View
•	MDA/Recall/P0226-63024980- 2022	MEDICAL TESTONA	31/03/9022		Notification	Draft	OF View
1	MDA/Recall/P0224-63671427- 2022		8/03/2022		Notification	Draft	(B) View
1	MDA/flucall/P0295-14772/48- 2022		31/03/2022		Notification	Draft	(B) View
۲.	MDA/Bacal/P30210-76486591 2022	MEDICAL TESTONR	\$6/03/2022	NL/04/9002	Notification	Draft	(B) Wood
	MDA/Recall/P0217-00467572- 2022	MEDICAL TESTOND	24/03/2022		Notification	Draft	OP View
7	MDA/fbecall/P0216-84700640- 2022	MEDICAL TESTOHD	10/03/2022		Notification	Draft	(B) View
Ŀ.	MDA/Recall/P0215-07236594- 2022		45/03/2022		Notification	Draft	(B) View
Ľ	MDA/Recell/P0254-74568046- 2022		16/03/2022		Notification	Draft	(B) Your

- a. Latest of Recall will be displayed as above:
 - 1. List of Report This table will display ten (10) latest reports of Recall.
 - 2. Click View button and the system will display the report. (Refer to **5.4 VIEW RECALL REPORT**)

2.5 SYSTEM NOTIFICATION

- a. System notification only focuses on reports with Overdue and almost Overdue status.
- b. There two (2) type of System Notification:

1. Notification Pop-up

I. Notification pop-up is to notify the user that there are report with Almost Overdue and Overdue status:

Alert! Please take note of these a	opplication !	Cli	ck "X" button	2 ×
Overdue Applications				
MPR				
The deadline to submit your investig possible to complete your incident		ase provide the inves	igation report as soo	n as
Disregard this message if investigat	ion report has been submitted.			
Please, Click Here to see all the not	ification list			
Click "Click Here" link		Click *Close	e' button 3	Close

- II. Notification pop-up will appear at the Dashboard (Refer to 2.3
 Dashboard) and will be displayed as above:
 - Click Click Here link and the system will redirect to the list of Notification as below:

0	Deveal NetReations	0	Read Notifications	
No.	RetNo	Mudul	Status	Action
1	MDA/MPR/P0275-756/50/9-2022	MPR	Almost Overdue	-
2	MCA/MPR/POIN-KEPUIT-XX22	MPR	Almost Overdae	View
3	MDA/FCA/P82367-6429266-3222	RCA	Almost Overdue	-
4	MDA/FGA/F034F-9098388F-2022	PCA	Almost Overflow	Ver
5	MDA/MPR/P0273-2458582-2022	MPR	Overdue	View

• Unread Notification tab

	Ground NatiPauliana		Read Not Reactions			
			4	lick "View" buttor		
No	But No	Modul	Distan	Action		
C	MDA/MPR/90275-7565869-2022	M870	Almost Overfax	View		
2	MDA/MP8/P0218-962/12/3 2022	1471	Almost Overdue	-		
0 (=	MDA/FCA/ROBE-601098-0020	FDA	Almost Overslav			
List of 4	MDA/FCA/PG2H-RONK268-2022	FDA	Almost Overdae	(Vine)		
Report	MOA/MPR/P0272-2408080-2022	METR	Overthee	View		

- List of Notifications This table will display a list of unread notifications for the report with Almost Overdue and Overdue status.
- Click View button and the system will display the report:
 - MPR (Refer to **3.5 VIEW**).
 - FCA (Refer to 4.4 VIEW REPORTING).
 - Recall (Refer to 5.4 VIEW RECALL REPORT).

• Read Notification tab

	Dread NotFeatlern		Read Notifications	
				Click "View" buttor
-	Set Set	Madel	Birton	Action
ſ	MDA/FCA/POSID-68708487-3021	FDA	Overillae	Ven
1	MDA/FCA/POEI2-88709407-3021	FDA	Almost Overdue	Vice
1.	MDAPCAPOZY MUMAR 2021	FEA	Overstan	View

- List of Notifications This table will display a list of read notifications for the report with Almost Overdue and Overdue status.
- Click View button and the system will display the report:
 - MPR (Refer to **3.5 VIEW**).

Close

- FCA (Refer to **4.4 VIEW REPORTING**).
- Recall (Refer to 5.4 VIEW RECALL REPORT).
- ➢ Click X button or

button to close the pop-up.

2. Notification Bell

	Click "I	Bell" button			
0	Search		*	0	

- I. icon button is located at the navigation bar
- II. Click *icon* button and the system will display a list of Unread Notification as below:

	Click "MDA/MPR/P0275-75615819-2022" link
1 Unread Notifications	MPR MDA/MPR/P0275-75615819-2022 are Almost Overdue 1WEEK AGO MPR MDA/MPR/P0274-95071273-2022 are Almost Overdue 1WEEK AGO
l	View all notifications 3 Click "View all notifications" button

- Unread Notifications are the list of unread Notifications for the report with Almost Overdue and Overdue status.
- > Click the "MDA/MPR/P0275-75615819-2022" link to view

the report and the system will open the view page:

- MPR (Refer to 3.5 VIEW).
- FCA (Refer to **4.4 VIEW REPORTING**).
- Recall (Refer to **5.4 VIEW RECALL REPORT**).

≻ Click

View all notifications

button and the system

will redirect to the list of Notification as below

0	Unread Notification tabs	2	ad Notification tabs	
	But No.	Madul	Status	Action
1	MCA/MPR/F0275 7505899-2022	MPR	Almost Overdue	-
2	MDA/MFR/P0274-8507073-2022	MPR	Almost Overdue	View
3	MDA/RCA/P85367-64210466-2022	FCA.	Almost Overdue	View
4	MEA/TCA/TESH-9099398-2022	FGA.	Almost Overdue	No.
5	MDA/MPR/P0272-2438582-2022	MPR	Overdue	View

• Unread Notification tab

	Ground NatiPauliana		Read Not Readows						
				lick 'View' buttor					
No	Bul No	Modul	Datas	Action					
6	MDA/MP3/P0275-7565886-2022	MITTE	Almost Overdue	View					
2	MDA/MP8/P0218-96070278-2022	Marcine .	Almost Overdue	-					
4	MDA/FCA/RIDBP-6/2022	FDA	Almost Dverslag						
4	MDA/FCA/PODH-ROMINAL-2022	FDA	Atmost Overdae	State 2					
1	MDA/MPR/P0073-2408080-2002	M572	Overthee	View					

- List of Report This table will display a list of unread reports that are Almost Overdue and Overdue.
- Click View button and the system will display the report:
 - MPR (Refer to **3.5 VIEW**).
 - FCA (Refer to **4.4 VIEW REPORTING**).
 - Recall (Refer to 5.4 VIEW RECALL REPORT).
- Read Notification tab

			Click "View" buttor
Ref No.	Madul	Birton	Action
MDA/FCA/POSID-68708687-3021	FGA	Overillae	Vee
MDA/FCA/POEI2-88709407-3021	FEA	Almost Overdue	Vice
MDA/FCA/PO229-95286432-2025	PEA	Overstan	- Veren
	MDA/FCA/P0232-83729407-3029	MGA-TCA-PGEID-6029467-3621 FGA MGA-TCA-PGEID-6029467-3621 FGA	MGA-TCA-POED-8293467-3291 FGA First Deerbus MGA-TCA-POED-8293467-3291 FGA Deerbus

List of Report - This table will display ten (10) latest reports of Recall. Click View button and the system will display the report:

- MPR (Refer to **3.5 VIEW**).
- FCA (Refer to **4.4 VIEW REPORTING**).
- Recall (Refer to 5.4 VIEW RECALL REPORT).

> Click \times button or button to close the pop-up.

2.6 USER PROFILE

				Click "Prof	ile" icc	on	•	
		0	Search			¢	0	
2	Tho	0	on hutton is lo	eated at the na	vigation	bor (con

a. The vicon button is located at the navigation bar. Click vicon button and the system will display the sub-menu:

Account 1 Click "Account"	" button
也 Logout	

b. The list of sub-menus will be displayed as above. Click ^a Account button and the system will open the user profile page.

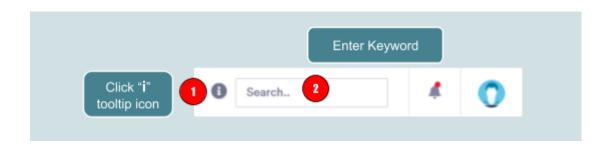
Dashboard > User Profile			
Edit Account			
Name	HOST Off	Enter Name	
Username	hostOft@test		
Email	pmax.dev@gmail.com 2	Enter Email	
Role	Superuser		Click "Submi button
			0

- c. The User Profile page will be displayed as above and the user required to fill the updated information:
 - 1. Please Enter the Updated Name.
 - 2. Please Enter the Updated Email.
 - 3. Click button and the user information are updated.
 - 4. Click ^{Change Password} button and the system will display the change password pop-up as below:

Change Password		Click "X" button 🚺 🗙
Current Password	1 Enter Current Password	2
New Password	2 Enter New Password	Reference in the second
Confirm Password	3 Enter Confirm Password	Eye" icon button
	Click "Close" button	Close Submit
		Click "Submit"

- I. Please Enter the Current Password.
- II. Please Enter the New Password.
- III. Please Enter the Confirm Password.
- IV. Click icon button, to view the password that you enter.
- V. Click the ^{Submit} button and the password is updated.
- VI. Click the \times button or button to close the pop-up.

2.7 SEARCH



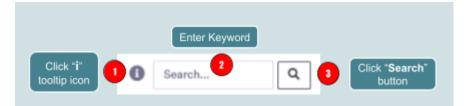
- a. The search box (input field) is located at the navigation bar as above:
 - 1. User can click ① icon and the pop-up information related to search will display as below:

I	nf	orr	nat	tio	n										(Clic	k '	X "	bı	itto	n		1	3	×
	t	ι.	Ту	o o	an R N R	efe led epc	eyw ren ical ort 1	ype	lun vic	e N	er lame our k		/bo	ar	d										
											Clic	ck	"C	lo	se	•" b	utt	on		ł		С	los	0	
							tto			c	lose														

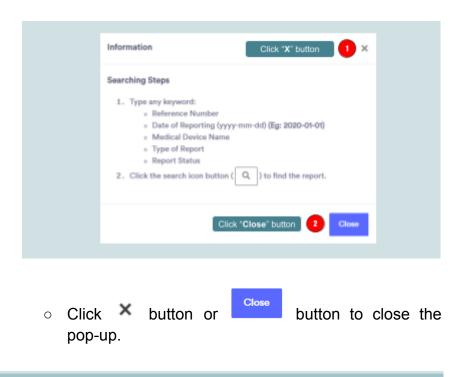
- 2. Enter any related keyword (based on information given).
- 3. Press the "**Enter**" key on the keyboard and the system will display the result as below:

hiboard	> Search Read				
Sear	rch Result				Table Filtering
No	Reference No.	Date of Reporting	Medical Device Name	Type of Report	Status Action
1	MDA/FCA/P0229-95246492- 2021	94/02/2022	MEDICAL TESTORC	Closure	Click "View" 2 Stew button
2	MDA/FCA/P0232-93729407- 2021	28/12/2021	MEDICAL TESTORD	Follow Up	Click "Log"
3	MDA/Recall/P017771029481- 2022	12/02/2022	MEDICAL TESTORIC	Final	Submitted
4	MDA-MPR/P0235-48740369- 2022	Reporting : 15/03/2022 Investigation : 15/03/2022	MEDICAL TESTOID	Application Type: Reporting Application Type: Investigation	Reporting Status: Submitted DView Investigation Status: Submitted
6	MDA/MPR/P0336-36966m0- 2022	Reporting : 13/03/2022 Investigation : 17/03/2022	MEDICAL TESTONE	Application Type: Reporting Application Type: Investigation	Reporting Status: Submitted @ View Investigation Status: Submitted
	MDA/MPR/P0237-32551200-	Reporting :	MEDICAL	Application Type:	Reporting Status:

I. Table Filtering



User can click icon and the pop-up information related to table filtering will display as below:



- > Enter any related keyword (based on information given).
- > Click $\[\] \alpha \]$ icon and the system will display the result.
- II. Click View button and the system will display the report:
 ➤ MPR (Refer to 3.5 VIEW).
 - ➤ FCA (Refer to 4.5 VIEW REPORTING).
 - ➤ Recall (Refer to **5.4 VIEW**).
- III. Click button and the system will display the pop-up list of Log as below:

ŧa.	Dete	Stege	Status	Officer
1	03/01/2022 16:01:35	Accept report	Report has been accepted	Nurul Diyana binti Mohd Nor
2	03/01/2022 16:06:22	Evaluation	Verb I texted her a little while ago. I texted a message to her. She just texted me back.	Nurul Diyana binti Mohd Nor
3	03/01/2022 16:06:22	Evaluation	Follow Up report has been Evaluated by HOST 011	Nurul Diyana binti Mohd Nor
4	28/01/2022 17:07:42	Almost Overdue	Field Corrective Action (FCA) report are almost Overdue	System
5	28/01/2022 17:09:07	Overdue	Field Corrective Action (FCA) Follow Up report has Overdue	System
			Click *Close" button	
			Chek Close Ballon	

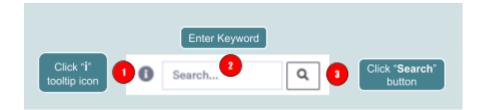
2.8 MY DEVICE

Dashboard MANDATORY PROBLEM REPORTING (MPR) FIELD CORRECTIVE ACTION (FCA) Click "MyDevice" Menu 1 MyDevice	м	ENU		
REPORTING (MPR) FIELD CORRECTIVE ACTION (FCA) Click "MyDevice" Menu	*	Dashboard		
Click "MyDevice"	•	MANDATORY PROBLEM		
Ø RECALL , Menu	٥	ACTION (FCA)	Click *MvDevice "	
	S			

- a. The Sidebar Menu will be displayed as above:
 - 1. Click MyDevice menu and the system will redirect users and display the list of devices.

My Device		
Dashboard > My Device		
List of My D	evice	Table Filtering
		2 0 Search Q
No.	Device Registration No.	Device Name
- ('	GMDTESTFORHOSTOMA	MEDICAL TESTONA
🚺 J 🚈	GMDTESTFORHOSTONB	MEDICAL TESTOHB
List of 8	GMDTESTFORHOSTORC	MEDICAL TESTORIC
evices 4	GMDTESTFORHOSTOHD	MEDICAL TESTOND
Showing 4 of 4 en	ries.	

- b. Page of My Device will be displayed as above:
 - 1. List of Devices are the list of registered devices from Medcast 2.0.
 - 2. Table Filtering



I. User can click (1) icon and the pop-up information related to table filtering will display as below:

Information	Click "X" button
Searching Steps	
 Type any keyword: Device Regist Medical Devi Click the search ico 	ce Name
	Click "Close" button 2 Close

- II. Enter any related keyword (based on information given).
- III. Click \bigcirc icon and the system will display the result.

3 MANDATORY PROBLEM REPORTING (MPR)

3.1 MANDATORY PROBLEM REPORTING (MPR) SIDEBAR



- a. Mandatory Problem Reporting (MPR) sidebar will be displayed as above:
 - 1. Create New Reporting : Display the new create page for Reporting. (Refer to 3.3 CREATE NEW REPORTING)
 - 2. Draft Reporting : Display the Reporting with a 'Draft' status. (Refer to 3.2.1 Draft Reporting)
 - Status of Submission Reporting : Display the list of reporting that have been submitted by the user. (Refer to 3.10.1 Status of Submission Reporting)
 - 4. Investigation Dashboard : Display the Investigation main dashboard. (Refer to 3.2.2 Investigation Dashboard)
 - Status of Submission Investigation : Display the list of investigation reports that have been submitted by the user. (Refer to 3.10.2 Status of Submission Investigation)

3.2 DASHBOARD

3.2.1 Draft Reporting

			2	6 Search.	٩
NO.	MPR REFERENCE NO.	MEDICAL DEVICE NAME	DATE (DD/MM/YY)	STATUS	ACTION
1	MDA/MPR/P0003-39494718-2022	MEDICAL TEST0108	01/04/2022	Draft	® View @FLdt I≣Log ₿Delete
2	MDA/MPR/P0002-39640331-2022	MEDICAL TEST010C	30/03/2022	Draft	® View Ø felt i≣ Log @ Delete
3	MDA/MPR/P0001-80990420-2022		24/03/2022	Dealt	View Edit Edit Edit Edit Delete

- a. The Draft Reporting page will be displayed as above:
 - 1. List of Draft
 - I. List of Draft will display the list of reporting that has been saved as draft.
 - 2. Table Filtering



I. Click icon to get more information related to table filtering and the pop-up will be displayed as below :

	Info	rmation Click "X" button
	Sea	rching Steps
		 Type any keyword:- MPR Reference Number Medical Device Name Date (yyyy-mm-dd) (Eg: 2020-01-01) Click the search icon button (Q) to find the report.
		Click "Close" button 2 Close
		> Click × button or button to close
	II.	the pop-up. Enter any related keyword (based on information
		given).
	III.	Click con and the system will display the result.
3.	Actio	n Button
	I.	Click View button to view the reporting that has been saved as draft and the view page (Refer to 3.5.1 View Mandatory Problem Reporting)
	II.	Click Click button to update the reporting. (Refer to 3.7.1 Edit Mandatory Problem Reporting)

III. Click **i** button to view the reporting log and the pop-up will be displayed as below :

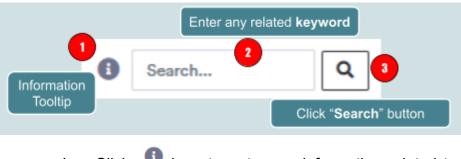
								•	
Mandatory	Problem Reporti	ng (MPR) L	og	Cli	ck " X '	" button		U	×
Applica	tion Log Details	: MDA/M	PR/P0307-2	4919272-2022					
NO.	DATE / TIME	STAGE		5	TATUS			USER	
1	15/03/2022 11:16:04	Draft	Mandatory as draft	Problem Report	ing (MPR)	report has bee	m saved	HOST 0ff	
			_						_
			[C	lick " Clo :	se" bi	utton	2	Close	
	×	Clic	< ×	button	or	Close	but	ton to	C
		the p	pop-up) .					
IV.	Click	Î D	elete	button	to	delete	e the	e rep	or

V. Click Delete button to delete the reporting. (Refer to 3.8 DELETE MANDATORY PROBLEM REPORTING)

3.2.2 Investigation Dashboard

ion Report					'Overdue Rep Table" tabs	porting
	Application Reporting 1 Click "Application			2 Overdue Reporti	ng Table (3) Table Filteri	ing
	Table" ta			•	Search	٩
NO.	MPR REFERENCE NO. MDA/MPR/P0306-22120696-2022	MEDICAL DEVICE NAME	DATE (DD/MM/YY) 30/03/2022	DUE DATE (DD/MM/YY) 29/04/2022	New	ACTION
2	MDA/MPR/P0314-59244598-2022	MEDICAL TESTORID	17/03/2022	16/04/2022	Draft	® View @f6dR I≣ Log
3	MDA/MPR/P0266-17793059-2022	MEDICAL TESTOTIB	18/02/2022	16/04/2022	Return from MDA	® View @fEdit i≣ Log

- a. The Investigation Dashboard page will be displayed as above:
 - 1. "Application Reporting Table" tabs
 - I. "Application Reporting Table" tabs will display the investigation report with the status of New, Draft and Return from MDA.
 - 2. "Overdue Reporting Table" tabs
 - "Overdue Reporting Table" tabs will display the investigation report with the status of Almost Overdue, Overdue and Extend Date. (Refer to 3.9 OVERDUE REPORTING TABLE)
 - 3. Table Filtering

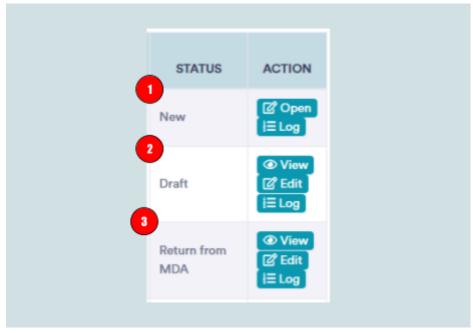


I. Click ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below :

Info	ormation Click "X" button 1 ×	
Sea	arching Steps	
	 Type any keyword:- MPR Reference Number Medical Device Name Date (yyyy-mm-dd) (Eg: 2020-01-01) Due Date (yyyy-mm-dd) (Eg: 2020-01-01) Status Click the search icon button (Q) to find the report. 	
	Click "Close" button 2 Close	
	Click × button or button to the pop-up.	close
II.	Enter any related keyword (based on inform given).	natior
11.	Click (a) icon and the system will displa result.	iy the

4. Action Button

I. Action button in the Investigation Dashboard will be displayed based on statuses as shown below :



- Status New : New investigation report that has not yet been opened and has not yet been filled out by the user.
 - Click Open button to create investigation report. (Refer to 3.4 CREATE INVESTIGATION REPORT)
 - Click <u>IE Log</u> button to view the investigation report log and the pop-up will be displayed as below :

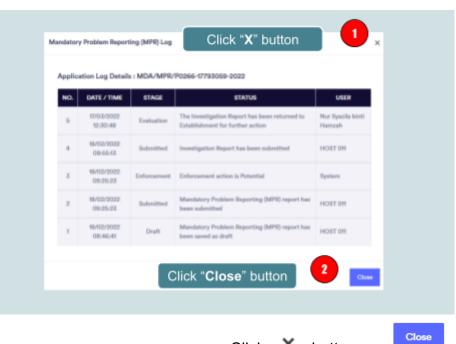
NO.	DATE / TIME	STAGE	STATUS	USER
2	30/03/2022 11:03:26	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST Off
1	15/03/2022 11:15:32	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST 011

- Click × button or button to close the pop-up.
- Status Draft : Investigation report that has been opened but has not yet been submitted by the user.
 - Click View button to view the investigation report. (Refer to 3.5.2 View Investigation Report)
 - Click Click button to update the investigation report (Refer to 3.7.2 Edit Investigation Report)
 - Click **Log** button to view the investigation report log and the pop-up will be displayed as below :

NO.	DATE / TIME	STAGE	STATUS	USER
2	30/03/2022 ft:03:26	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST Off
1	15/03/2022 11:15:32	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST 0ff

 Click × button or button to close the pop-up.

- Status Return From MDA : Investigation report that has been returned by the MDA for the user to update an incomplete report or there are corrections that need to be updated.
 - Click View button to view the investigation report that has been returned from MDA. (Refer to 3.5.3 View Return From MDA)
 - Click Cedit button to update the investigation report that has been returned from MDA. (Refer to 3.7.3 Edit Return From MDA)
 - Click button to view the investigation report that has been return from MDA log and the pop-up will be displayed as below :



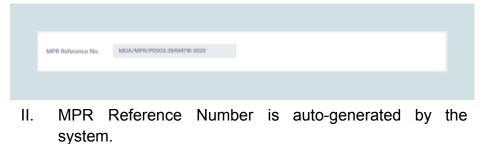
■ Click × button or button to close the pop-up.

3.3 CREATE NEW REPORTING

Figure X shows flow-chart of the steps to be taken by user before making submission for Mandatory Problem Reporting under Section 40 of Act 737

Mandatory Problem Re	porting (MPR)
Mandatory Problem Reporting Form	
	MANDATORY PROBLEM REPORTING FORM
	Medical Device Act 2012 (ACT 737)
	Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019
(*)-maginal	
This page DOES NOT HAVE AN AUTO S	SAVE FUNCTION. Please click the BACK BUTTON at the bottom of the page and click the SAVE AS DRAFT in the confirmation box.
MPR Reference No.	MDA-MPE/70003-3949478-2022 MPR Reference Number
* Section A : Location of Incident	Section A : Location of Incident
 Section 8 : Background Information 	Section B : Background Information
 Section C : Device Information 	Section C : Device Information
 Section D : Incident Informatio 	5 Section D : Incident Information
Declaration	Declaration
I hereby attest that the informa-	tion and attachment provided on this reporting is / are correct, completed and current to this date.*
I understand and acknowledge	that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.
Person Responsible for the Establishment	HOST 011
Job Title	MANAGER
Telaphona	0123466789
Email Address	hastOff@setureburg.com Button Section
	Back Claur Previous PDF Submit

- a. The Create New Reporting page will be displayed as above :
 - 1. MPR Reference Number
 - I. MPR Reference Number will be displayed as below :



2. Section A : Location of Incident

I. Section A will be displayed as below :

♥ Section A : Location	n of Incident
Where the incident occurred*	In Malaysia Outside Melaysia

- User must select one of the radio button whether the location of the incident is in Malaysia (In Malaysia) or outside Malaysia (Outside Malaysia).
- III. If the user select O In Malaysia
 - > The pop-up will be displayed as below :

If incident occurred in	Malaysia : ×	
Type of affected facility*	Government hospital / clinic Private hospital / clinic Unknown Others	
Name of institution/ Incident Location*		
Address Line 1*		
Address Line 2*		
Postcode*		
City*		
Statu*	Select State *	
Telephone no.*	Telephone an anothe at least 10 sumbers	
Fax no.	Fat on small be F masshers	
Contact person at site of incident*	1	Click
ick " Clear " button	2 Car Codes	"Confirm" button

User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).

 \succ Click button to close the pop-up.

- Click button to clear the form in the pop-up.
- IV. If the user select Outside Malaysia

 \succ The pop-up will be displayed as below :

- User are required to select the name of the country where the incident occurred in the dropdown button.
- \succ Click button to close the pop-up.
- 3. Section B : Background Information
 - I. Section B will be displayed as below :

 Section 8 : Backgroun 	d information	
1. Date of Reporting	81/03/2022	
2. Date of Incident*	24/03/2022	
	Category 2 : Led to death of a patient, use	c; Deterioration of device effectivaness; Inadequacy in labelling or IFU. r or other person; Led to serious deterioration in the state of health of a patient, user sath or serious deterioration in the state of health of a patient, user or other person or to recut.
4. Date of establishment aware on the incident*	28/03/2022	
	Important	
	Celegory 1, MPR report shall be submitted within 30 days from the date of establishment aware on the incident	
5. Time period of	7 days	
reporting from the date of incident		

- User are required to fill in all fields that marked with an asterisk (*). For question Number 1 (Date of Reporting) will fill in automatically based on current date.
- III. Important notice will be displayed as below based on the radio button category that has been selected in question Number 3 (Report Category).

Important
Category 1, MPR report shal be submitted within 30 days from the date of establishment aware on the incident
Important
Category 2, MPR report shall be submitted within 10 days from the date of establishment aware on the incident
9 Important
Category 3, MPR report shall be submitted within 2 days (48 hours) from the date of establishment aware

IV. For question Number 5 (Time period of reporting from the date of incident), the system will fill in automatically once the user selects the date on question Number 2 (Date of Incident). This time period indicates the period of how many days the user took to report from the Date of Incident. Question Number 5 will be displayed as below :

5. Time period of 7 days
reporting from the date of incident

V. If the user select the date on question Number 4 (Date of establishment aware on the incident) more than the specified period from the date on question Number 1 (Date of Reporting), the Justification text area will be displayed as below :

 Section B : Backgro 	and information	
1. Date of Reporting	31/03/2022	
2. Date of Incident*	24/03/2022	
 Report Category* A. Date of establishmer 	Category 2: Led to death of a patient, use or other person; May led to d could do so were the incident Category 3: Berious threat to public healt	c Deterioration of device effectiveness; inadequacy in labelling or IFU. r or other person; Lad to serious detarioration in the state of health of a patient, user each or serious deterioration in the state of health of a patient, user or other person or to recut.
aware on the incident*	R 201 007 2022	
	Important	
	Category 3, MTR report shall be submitted within 2 days (48 hours) from the date of establishment aware on the incident	
	This field is required. Minimum 4	0 characters.
	Under the Act 757, your reporting h Therefore please state your justified	as been exceeded the specified reporting timeframe.

- VI. User need to fill in the text area to justify the delay of the period that has been set according to the act. The minimum number of characters for this field is 40 characters. If user does not fill in more than 40 characters, user will not be able to submit the reporting.
- 4. Section C : Device Information
 - I. Section C will be displayed as below :

Andical Device Ingistration No.	Select Medical Device Re	gistration No.		
Device Name				
hand Name				
Jam of Device				
Annelacturer Name				
				4
		Table of Affecte	d Devices	
NO.	BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE
No list to display				

- II. User are not required to fill in this field because the field for Section C is not mandatory for reporting.
- III. Click the dropdown button to select Medical Device Registration No.
- IV. All questions will be automatically filled by the system according to the Medical Device Registration No. that the user has been selected except for Table of Affected Devices.

Add Details of Affected Devices

V.

button will be enabled after the user fills in the Medical Device Registration No. in Question 1.

Add Details of Affected Devices

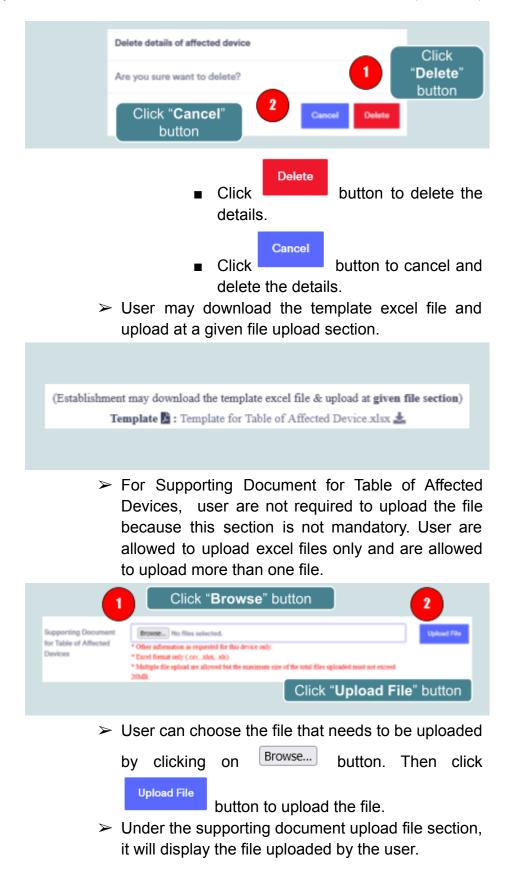
VI. By clicking button, the system will display Details of Affected Devices page shown as below :

Mandatory Problem Reporting (MPR)
And Devices And Devices 1 Click "Add Details" button 2 Table of Affected Devices
NO. BATCH NO. LOT NO. SERIAL NO. EXPIRY DATE ACTION 1 A4560
3 Supporting Document Image: Supporting Document
for Table of Affocted • Other information is requested for this device only. Devices • Scant flemant only (.orv, xim, xit) • Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 2005. Image: Statistic of Afforcted Device(0) (MDA_MPR_P0003_30404766_2022) Image: Statistic of Afforcted Device(0) (MDA_MPR_P0003_30404766_2022)
6 Next 50 with
Add Details button to add the details of the affected devices and the pop-up will be displayed as below :
Add details of affected devices
• Please fill in one (1) information from the four (4) elements displayed
Batch no.
Lot no.
Serial no.
Expiry Date dd / mm / yyyy 1 Click "Add" button
Click "Clear" Add button

User can fill in only one (1) information from the four (4) elements displayed.

- After user fill in the field, click dd button to store the information into the Table of Affected Devices.
- Click button to clear the form in the pop-up.
- If user wants to fill in the next details, user need to click
 Add Details
 button again.
- In the Action column, there are two (2) buttons that user can use which is :
 - Click Click button to update the details of affected devices in the table. The pop-up will be displayed as below :

Update details of affecte	d devices	×
Batch no.	A4560	
Lot no.		
Serial no.		
Expiry Date	dd / mm / уууу	n
Click " Cle a button		Update Click "Update"
		button
•	Click Update but the details.	itton to update
-	Click butto form in the pop-up.	on to clear the
 ○ Click from t as bel 	he table. The pop-up	elete the details will be displayed





5. Section D : Incident Information

I. Section D will be displayed as below :

✓ Section D : Incider	at Information
1. Incident occurred related to*	Patient Device Interaction Problem Annufacturing, Packaging or Shipping Problem Charnical Problem Annufacturing, Problem Detrical Problem Calibration Problem Calibration Problem Canput Problem Computer Problem Computer Problem Computer Problem Computer Problem Calibration Calibration Computer Problem Calibration
	Connection Problem Connection Problem Connection Problem Kativation, or Transmission Problem Contamination, Positioning or Separation Problem Compability Problem Contamination / Decontamination / Decontami

2. Description of incident*	
3. Device operator during time of incident	Healthcare Professional Patients Others
4. Usage of device* Please select two (2)	initial Use ifingie Use / Disposables Reuse of Reusable Reuse of Reusable Reserviced / Refurbished Others
6. Current location of the device Note: Information on state of device is at the time of the report	
6. List of other devices involved in the incident (if applicable)	
7. Immediate Action taken by the entablishment during incident	
8. Submission of Investigation Report*	Within 30 days after submission Request for extension Request for extension time:

II. User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).

6. Declaration

I. Declaration will be displayed as below :

Declaration	
Thereby attest that the	information and attachment provided on this reporting is / are correct, completed and current to this date.*
I understand and acks or misloading.*	owindge that is an offence under Section 76 of Act 737, to make sign or familah any declaration, or other document which is untrue, inaccurate
Person Responsible for the Establishment	HDST 04
tor the Catabilitienters.	
Job Title	MANAGER
lidephone	0123454/99
Email Address	hast018jedsundung.com

- II. User are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are :
 - ➤ Name of Reporting Person

- ➤ Job Title
- ➤ Telephone
- ➤ Email Address

7. Button Section

I. Button section will be displayed as below :



II. Click button to go back to the previous page. There will be two (2) types of pop-up that will be displayed as below :

1	Back Confirmation Pop-up			
•	Back Confirmation		×	
	Are you sure to back to the previous page?		2	
	Click " No " button	3	No Yes	
			Click "Yo buttor	

Back Confirmation Pop-up

 If the question Table of Affected Devices in Section C has been filled, this Back Confirmation pop-up will be displayed.

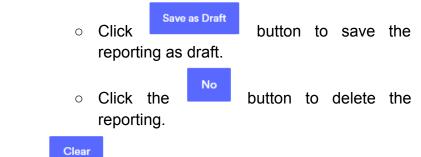


• Click the button to stay on the same page.

1	Draft Confirmation Pop-up	
•	Draft Confirmation ×	
	Changes you make will be lost if you navigate away from this page. Do you want to leave this page AND SAVE AS DRAFT?	
	3 No Save as Draft Click "No" button	
	Click "Save a Draft" buttor	

> Draft Confirmation Pop-up

 If the question Table of Affected Devices in Section C has not been filled, this Draft Confirmation pop-up will be displayed.



- III. Click button to clear all the information in the reporting except the default value.
- IV. Click button to preview the reporting in Portable Document Format (PDF) format. (Refer to 3.6.1 Preview PDF Mandatory Problem Reporting)
- V. Click button to submit the reporting. This button will be enabled once the user tick both of the checkboxes in the Declaration section.

3.4 CREATE INVESTIGATION REPORT

Figure X shows flow-chart of the steps to be taken by user before making submission for Investigation Report under Section 40 of Act 737

Section 40		ESTIGATION	FORM	
Section 40				
Section 40	Medic	cal Device Act 2012	(ACT 737)	
orection way	, Act 737 and Regulation 5 Med	lical Device (Duties and (bligations of Establishmen	t) Regulations 2019
besiuper-(*)				
This page has an AUTO SAVE FUNCTION	N. Your form would be saved automa	tically as you make progress	on the browser. Please be cauti	ious with your case details.
		-		
MPR Reference No. MDA	A/MPR/P0314-59244598-2022		MPR Reference	Number
	2 Section A	: Device Informat	ion	
 Section A : Device Information 				
 Section B : Results of Manufacture 	3	Section B : Resi	ilts of Manufacturer	Investigation
 account b : Resons or Manufacto 	arer invesogation	000.000 00000		
 Section C : Patient Information 				
	Section C :	Patient Informatio	in	
6 1	Declaration			
Declaration	Deciaration			
I hereby attest that the informati	tion and attachment provided on t	this reporting is / are-corre	t, completed and current to t	this date.•
I understand and acknowledge t	that is an offence under Section 7	6 of Act 737, to make sign o	r furnish any declaration, or o	other document which is untrue, inaccurate
or misleading.*				
Person Responsible HOST	IT 011			
for the Establishment				
Job Title MAN	NAGER			
Telephone 01234	456739			
Email Address host	0118sebumbung.com			Button Section
				Bakon Section
				Back Clear Preview PDF Submit

a. The Create Investigation Report page will be displayed as above :

1. MPR Reference Number

I. MPR Reference Number will be displayed as below :

MPR Reference No. MDA/MP0/10204-00204000-0022

- Π. MPR Reference Number is auto-generated by the system.
- 2. Section A: Device Information
 - Ι. Section A will be displayed as below :

Medical Device Registration No.	Select Wedical Device Rep	platration No.		
Device Name				
Brand Name				
Class of Device				
Manufacturer Name				
			Å	
		Table of Affecte	d Devices*	
ND.	BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE
		No list to d	isplay	
11 - 12 - 6 17 - 1 24	/ Add Detai		1	

- II. User are required to fill in this field because the field for Section A in the Investigation Report is mandatory. If user already fills in Device Information in Mandatory Problem Reporting (MPR), the data will be displayed in this section.
- III. Click the dropdown button to select Medical Device Registration No.
- IV. All questions will be automatically filled by the system according to the Medical Device Registration No. that the user has been selected except for Table of Affected Devices.

Add Details of Affected Devices

V.

VI.

button will be enabled

after the user fills in the Medical Device Registration No. in Question 1.

Add Details of Affected Devices

the button,

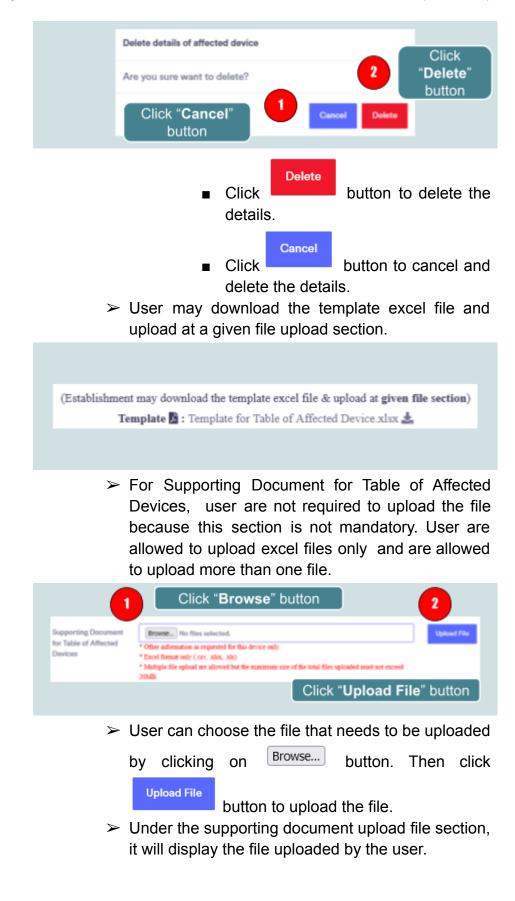
By clicking system will display Details of Affected Devices page shown as below :

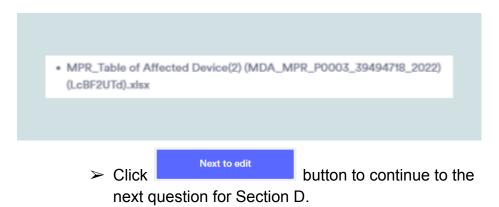
Mandatory Problem Reporting (MPR)
And Devices And Devices Details " button Table of Affected Devices
NO. BATCH NO. LOT NO. SERIAL NO. EXPIRY DATE ACTION 1 A4560
3 Supporting Document Image: Supporting Document
for Table of Affocted Periods Provide and Period Pe
6 Next 50 with
Click Add Details button to add the details of the affected devices and the pop-up will be displayed as below :
Add details of affected devices
• Please fill in one (1) information from the four (4) elements displayed
Batch no.
Lot no.
Serial no.
Expiry Date dd / mm / yyyy 1 Click "Add" button
Click "Clear" Add button

User can fill in only one (1) information from the four (4) elements displayed.

- After user fill in the field, click dd button to store the information into the Table of Affected Devices.
- Click button to clear the form in the pop-up.
- If user wants to fill in the next details, user need to
 Add Details
 button again.
- In the Action column, there are two (2) buttons that user can user which is :
 - Click Click button to update the details of affected devices in the table. The pop-up will be displayed as below :

Update details of affecte	d devices	×
Batch no.	A4560	
Lot no.		
Serial no.		
Expiry Date	dd / mm / уууу	•
Click " Cle a button	ar" 2 Close	Update Click "Update"
		button
•	Click the details.	button to update
•	Click Clear b form in the pop-up	outton to clear the
 Click from t as bel 	he table. The pop-	o delete the details up will be displayed





- 3. Section B : Results of Manufacturer Investigation
 - I. Section B will be displayed as below :

 Section 8 : Result 	s of Manufacturer Investigation	
1. Investigation finding	gs* 🗋 Biological Problem Identified	
	Electrical Problem Identified	
	 Electromagnetic Compatibility Problem Identified 	
	Interoperability Problem Identified	
	 Labelling and Instructions for Use / Maintenance 	
	Material and / or Chemical Problem Identified	
	Mechanical Problem Identified	
	Optical Problem Identified	
	Clinical Imaging Problem Identified	
	Software Problem Identified	_
	Thermal Problem	-
	Protective System Problem Identified	
	Operational Problem Identified	
	Patient Sample Problem	
	Environment Problem Identified	
	Manufacturing Process Problem Identified	
	Maintananoe Problem Identified	
	Transport / Storage Problem Identified	
	No Device Problem Found	
	No Findings Available	
	Results Pending Completion of Investigation	
	Appropriate Term / Code Not Available	
2. Root cause of the incident*		

3. Corrective Action and	O Yes
Preventive Action has been taken by the manufacturer*	O No
4. In Malaysia, this MPR	○ Yes
leads to FCA and Recall Action?*	No action required
5. Investigation report provided?* ()	Brougers No files selected. * Re-optimal files will deiter all pervision files. * Multiple file upload are allowed but the maximum size of the total files uploaded must are exceed 32040.
6. Was this incident reported to other Regulatory Authorities?*	○ Yes ○ No
	29/04/0022

- User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).
- III. For question Number 4 (In Malaysia, this MPR leads to FCA and Recall Action?), when user select 'Yes' in the radio button, a checkbox will be displayed as below :

			aysia, this MI	PR 💽 Yes					
		leads to F Recall Ac		FCA					
		Roodin Pio		Reca	11				
				O No acti	on re	quired			
IV.	User ne	ed to	choose	whether	to	open	а	repor	t for
	🖌 FCA	only,	🗹 Red	call only	or	both	~	FCA	and

- Recall from the investigation report.
- V. The FCA and Recall will be automatically opened through the investigation report after user submits the investigation report.
- VI. Click ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

A forget the set	
	Click "Close" button
≻ Click × pop-up.	button or button to close the

4. Section C : Patient Information

I. Section C will be displayed as below :

 Section C : Patient Inform 	rlion			
	т	able of Patient Information*		
AGE	PATIENT		PATIENT OUT	COME
No list to display				
Click "Ad	Id Patient In button	formation"	1	Add Patient Information

 II. Section C will be appeared when user chooses based on the situation as below in Mandatory Problem Reporting (MPR):

➤ Situation 1

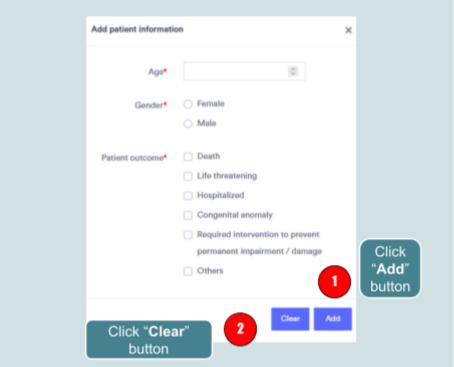
➤ Situation 2

Type of affected facility*	 Government hospital / clinic Private hospital / clinic Unknown Others
5. Current location of the device Note : Information on state of device is at the time of the report	 Remain implanted Explanted Disposed Quarantined at user's site Quarantined at establishment's site Returned to manufacturer Others

III. If user does not select one of the elements based on the situation as above, the Section C display will not be displayed on the investigation report.

IV. By clicking Add Patient Information button, the system will display Patient Information page shows as below :

Mandatory Problem R Dathbard > Instalgetion Form > Add P Add Patient Information	Glick Add	Action Button
AGE GENDER 1 45 Female 2 40 Male	PATIENT OUTCOME	2 ACTION (7 Eds. (2 Dates mage) (7 Eds. (2 Dates) 3
	4	Sea New York
	Add Patient Information b prmation and the pop-up w pow :	outton to add patient vill be displayed as



- User are required to fill in all fields that marked with an asterisk (*).
- After user fill in the field, click button to store the information into the Table of Patient Information.

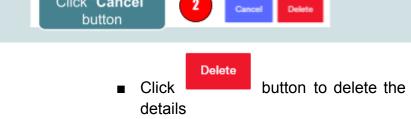
- Click button to clear the form in the pop-up.
- \succ If user wants to fill in the next details, user need to

```
Add Patient Information
```

button again.

- In the Action column, there are two (2) buttons that user can use which is :
 - Click Click button to update the details of patient information in the table. The edit patient information page will be displayed as below :

Mandatory Prob	lem Reporting (MPR)
editori i inesignioches	
Edit Patient Inform	nation
Auge*	4 1
Gender*	Foruite
Patient automore*	
	Congenital anomaly Begind intervention to present perspect (requirement / decays) Others
	2m (mm
	 Click Update button to update the patient information.
	 Click Delete button to delete the details of patient information from the table. The pop-up will be displayed as below :
	Delete Patient Information Click
	Are you sure want to delete the form?
	Click "Cancel"





5. Declaration

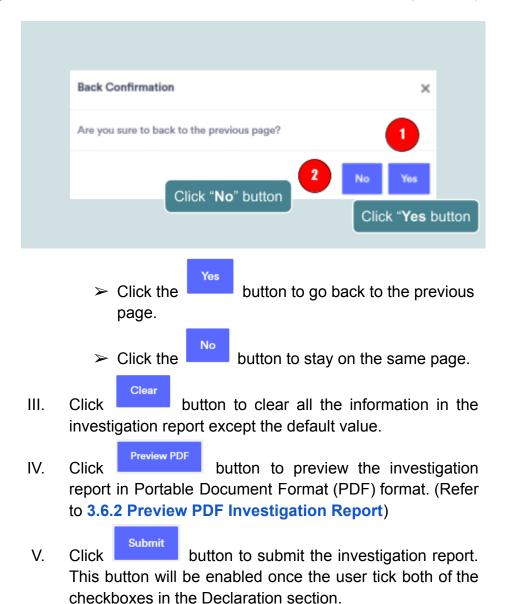
I. Declaration will be displayed below :

Declaration	
I hereby attest that the	e information and attachment provided on this reporting is / are correct, completed and current to this data.*
I understand and ackn or misloading.*	owiedge that is an offence under Section 76 of Act 737, to make sign or familah any declaration, or other document which is untrue, inaccurate
Person Responsible for the Establishment	H9 TBCH
Job Title	MANAGER
Tolephone	0123456709
Email Address	had0198edumbung.com

- II. User are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are :
 - ➤ Name of Reporting Person
 - > Job Title
 - ➤ Telephone
 - ➤ Email Address
- 6. Button Section
 - I. Button section will be displayed as below :



the confirmation pop-up message will be displayed as below :



3.5 VIEW

3.5.1 View Mandatory Problem Reporting (MPR)

a. Click •View button to view the reporting and the view page will be displayed as below :

andatory Problem Reporting (MF	PR)	
Mandatory Problem Reporting Form		
MANDATORY PROBLEM REPORTING FORM Medical Device Act 2012 (ACT 737)		
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019		
MPR Reference No.	MDA/MPR/P0306-22120595-2022	
Section A : Location of Incident		
Section A : Location of Incident		
Section A : Location of Incident Where the incident occurred	Outside Malaysia	

Section 8 : Background Information		
1. Date of reporting	30/03/2022	
2. Date of incident	22/03/2022	
3. Report category	Category 1 Failure of device affectiveness; Deterioration of device effectiveness; Inadequacy in labelling or IFU. 	
4. Date of establishment aware about the incident	23/03/2022	
5. Time period of reporting from the date of incident	8 days	

Section C : Device Information		
1. Medical device registration no.	GMDTESTFORHOSTORD	
2. Device name	MEDICAL TESTOND	
3. Brand name	TESTOND	
4. Class of device	D	
5. Manufacturer name	MANUFACTURER 011	
6. Details of affected devices	BATCH NO. LOT NO. SERIAL NO. EXPREY DATE	
 Declass of affected devices 	No list to display	
7. Supporting Document for Table of Affected Devices	 MPR_Table of Affected Device(1) (MDA_MPR_P0306_22120595_2022) (pAAj8(H1).xlox 	

Section D : Incident Information			
5. Incident occurred related to		Connection Problem Activation, Positioning or Separation Problem Installation-Related Problem Adverse Event Without Identified Davice or Use Problem	
2. Description of incident		Process output for establishment license for 2015 KPI - 21 working days with complete application	
3. Device operator during time of in	ncidamt	Healthcare Professional	
4. Usage of device		 Single Use / Disposables Reuse of Reusable 	
5. Device disposition / current loca	tion	Disposed	
6. List of other devices involved in	the accident		
7. Immediate action taken by the or	tablishment during incident		
8. Submission of Investigation Report		Within 30 days after submission	
	nation and attachment provided on this reporting is / are correct go that is an offence under Section 76 of Act 737, to make sign or HOST 011 MANAGER 0923466789 Next0100eebumbung.com	t, completed and current to this date. * furnish any declaration, or other document which is untrue, inaccurate or minimading. Clicck "Preview PDF" button	
		Click "Back" button	

- 1. Click PDF button to preview the reporting and the system will generate the Portable Document Format (PDF) format. (Refer to 3.6.1 Preview PDF Mandatory Problem Reporting)
- 2. Click button to return to the previous page.

3.5.2 View Investigation Report

a. Click view button to view the investigation report and the view page will be displayed as below :

andatory Problem Reporting (MPR)		
INVESTIGATION FORM Medical Device Act 2012 (ACT 737) Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019		
MPE Bularence No.	MDA/MP0/P0235-48710369-2022	
Section A : Device Information		
1. Madical device registration no.	GMOTESTFORHOSTOHD	
2. Device name	MEDICAL TESTORD	
3. Brand name	TESTOND	
4. Class of device	D	
5. Manufacturer name	MANUFACTURER OH	
6. Details of affected devices	BATCH NO. LOT NO. SEEBAL NO. EXPLICY DATE 450-500 0x02/2022 0x02/2022	
2. Supporting Document for Table of Affected Devices	No file attached	
Section 8 : Results of Manufacturer Investigation		
1. Investigation findings	Optical Problem Identified Software Problem Identified Operational Problem Identified Environment Problem Identified	
2. Root cause of the incident	Corrective Action and Proventive Action has been taken by the manufacturer	
3. Corrective Action and Proventive Action has been taken by the manufacturer	Yes	
4. In Maleysia, this MPR leads to FCA and Recall Action?	Yes + FCA + Recall	
5. Investigation report provided?	+ 3010 (MDA_MPR_P0235_48210348_2022) (C3(phup6).pdf	
6. Was the incident reported to other Regulatoy Authorities?	Yes * Australia * Canada	
7. Submission Date of Investigation Report	18-03-2022	

Declaration	
I hereby attest that the is	information and attachment provided on this reporting is / are correct, completed and current to this date.
I understand and acknow	eledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or mideading.
Person Responsible	HOET OH
for the Establishment	
Job Title	MANAGER
Talaphone	Ottakicija
(angrates)	PDF' button
Email Address	hoxi0119babumbung.com
	Click "Back" button 2 Inck Preview PDF
	Preview PDF
1.	Click button to preview the investigation report and
	the system will generate the Portable Document Format (PDF)
	format. (Refer to 3.6.2 Preview PDF Investigation Report)

2. Click button to return to the previous page.

3.5.3 View Return From MDA

- a. Click •View button to view the investigation report that has been returned from MDA.
 - The view page for status Return from MDA is the combination of the view page of Mandatory Problem Reporting (MPR) (Refer to 3.5.1 View Mandatory Problem Reporting) and the view page of Investigation Report (Refer to 3.5.2 View Investigation Report).

3.6 PREVIEW PDF

4. Date of establish

3.6.1 Preview PDF Mandatory Problem Reporting (MPR)

a. There are two (2) types of Preview PDF :

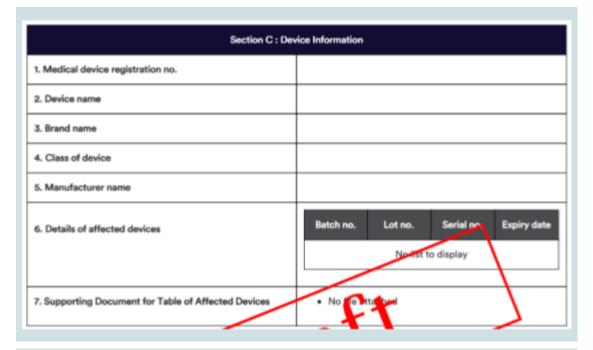
e about the incident

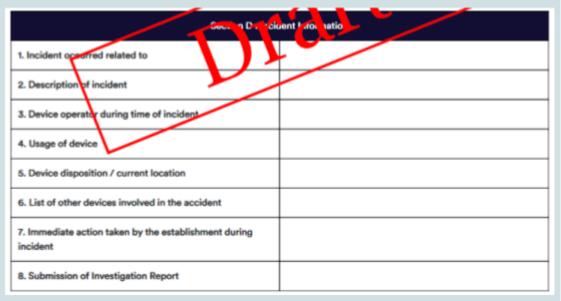
5. Time period of reporting from the date of incident

1. Preview PDF for Draft Report will be shown as below :

Medical Device AUTHORITY MALAYSIA MANDATORY PROBLEM REPORTING FORM Medical Device Act 2012 (ACT 737)					
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019					
MPR Reference No.	MDA/MPR/P0316-73777966-2022				
Section A : Location of Incident					
Where the incident occurred					
Section B : Backgroutal Information 1. Date of reporting 01/04/202 2. Date of incident 16/03/022 3. Report category Category 1 • railure of device affectiveness; • Deterioration of device effectiveness; • Inadequacy in labelling or IFU.					

8 days





I. The Declaration section will not be included in the Preview PDF for Draft Report.



Section B : Background Information		
1. Date of reporting	30/03/2022	
2. Date of incident	22/03/2022	
3. Report category	Category 1 Failure of device affectiveness; Deterioration of device effectiveness; Inadequacy in labelling or IFU. 	
4. Date of establishment aware about the incident	23/03/2022	
5. Time period of reporting from the date of incident	8 days	

2. Preview PDF for Submitted Report will be shown as below :

Section C : Device Information				
1. Medical device registration no.	GMDTESTFORHOST011D			
2. Device name	MEDICAL TEST011D			
3. Brand name	TEST011D			
4. Class of device	D			
5. Manufacturer name	MANUFACTURER 011			
6. Details of affected devices	Batch no. Lot no. Serial no. Expiry date			
	No list to display			
7. Supporting Document for Table of Affected Devices	 MPR_Table of Affected Device(1) (MDA_MPR_P0306_22120595_2022) (gAAj8jtH).xlsx 			

Section D : Incident Information		
1. Incident occurred related to	 Connection Problem Activation, Positioning or Seperation Problem Installation-Related Problem Adverse Event Without Identified Device or Use Problem 	
2. Description of incident	Process output for establishment license for 2015 KPI – 21 working days with complete application	
3. Device operator during time of incident	Healthcare Professional	
4. Usage of device	Single Use / Disposables Reuse of Reusable	
5. Device disposition / current location	Disposed	

6. List of other devices involved in the accident			
7. Immediate action taken by the establishment during incident			
8. Submission of Investigation Report	Within 30 days after submission		
Declaration			
Person Responsible for the Establishment	HOST 011		
Job Title	MANAGER		
Telephone Number	0123456789		

3.6.2 Preview PDF Investigation Report

- a. There are two (2) types of Preview PDF :
 - 1. Preview PDF for Draft Report will be shown as below :

INVESTIGATION FORM Medical Device Act 2012 (ACT 737)				
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment)				
Regulations 2019				
MDA/MPR/P0314-59244598-2022				
Section A : Device Information				
GMDTESTFORHOST011				
MEDICAL TEST011D				
TEST011D				



Section B : Results of Ma	anufacturer Investigation
1. Investigation finding	Clinical Imaging Problem Identified
	Operational Problem Identified
2. Root cause of the incident	
3. Corrective Action and Proventive Action has been taken by the manufacturer	
4. This MPR leads to FCA and Recall Action?	
5. Investigation report provided?	
6. Was the incident reported to other Regulatoy Authorities?	
7. Submission Date of Investigation Report	16/04/2012



I. The Declaration section will not be included in the Preview PDF for Draft Report.

2. Preview PDF for Submitted Report will be shown as below :



INVESTIGATION FORM

Medical Device Act 2012 (ACT 737)

Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019

MPR Reference No.

MDA/MPR/P0235-48710369-2022

Section A : Dev	vice Information
1. Medical device registration no.	GMDTESTFORHOST011D
2. Device name	MEDICAL TEST011D
3. Brand name	TEST011D

4. Class of device	D			
5. Manufacturer name	MANUFACTU	RER O11		
6. Details of affected devices	Batch no.	Lot no.	Serial no.	Expiry date
	450-500			
				01/02/2022
7. Supporting Document for Table of Affected Devices	No file at	tached		

Section B : Results of Ma	anufacturer Investigation
1. Investigation finding	 Optical Problem Identified Software Problem Identified Operational Problem Identified Environment Problem Identified
2. Root cause of the incident	Corrective Action and Preventive Action has been taken by the manufacturer
3. Corrective Action and Proventive Action has been taken by the manufacturer	Yes
4. This MPR leads to FCA and Recall Action?	Yes • FCA • Recall

5. Investigation report provided?	 3010 (MDA_MPR_P0235_48710369_2022) (iO3jduqS).pdf
6. Was the incident reported to other Regulatoy Authorities?	Yes • Australia • Canada
7. Submission Date of Investigation Report	13/03/2022

Decla	ration
Person Responsible for the Establishment	HOST 011
Job Title	MANAGER
Telephone Number	0123456789
Email Address	host011@sebumbung.com

3.7 EDIT

3.7.1 Edit Mandatory Problem Reporting (MPR)

a. A part of the Edit Mandatory Problem Reporting (MPR) page will be displayed as below :

5. Current location of	O Remain implanted
the device Note : Information on	O Explanted
state of device is at	O Disposed
the time of the report	Quarantined at user's site
	Quarantined at establishment's site
	Returned to manufacturer
	O Others
6. List of other devices involved in the incident	Loren losun
(if applicable)	
	A
7. Immediate Action taken by the	
establishment during	
incident	
8. Submission of	Vithin 30 days after submission
Investigation Report*	Request for extension time:

- 1. Users can update all information in this report.
- 2. The process to submit the updated reporting will be the same as submitting a new report. (Refer to 3.3 CREATE NEW REPORTING)

3.7.2 Edit Investigation Report

a. A part of the Edit Investigation Report page will be displayed as below:

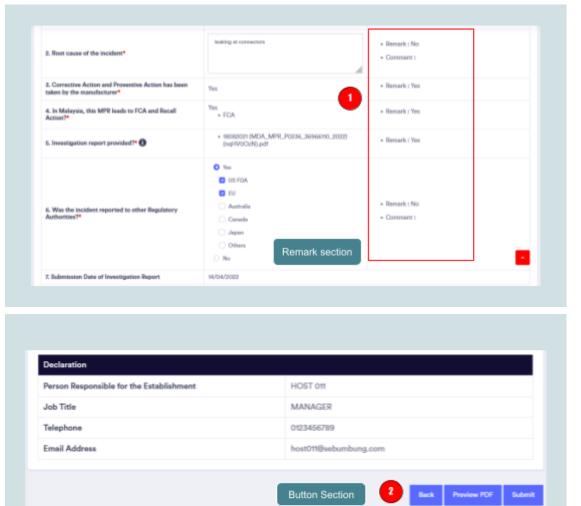
2. Root cause of the incident*	Lecere Ipsuri	
5. Corrective Action and Preventive Action has been taken by the manufacturer*	 Yes No 	
4. In Malaysia, this MPR leads to FCA and Recall Action?*	Yes FCA Recall No action required	
5. Investigation report provided?"	Rrowsen. No files selected. * Re-spicad files will delete all previous files. * Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20485.]

1. Users can update all information in this investigation report.

2. The process to submit the updated investigation report will be the same as submitting a new investigation report. (Refer to **3.4 CREATE INVESTIGATION REPORT**)

3.7.3 Edit Return From MDA

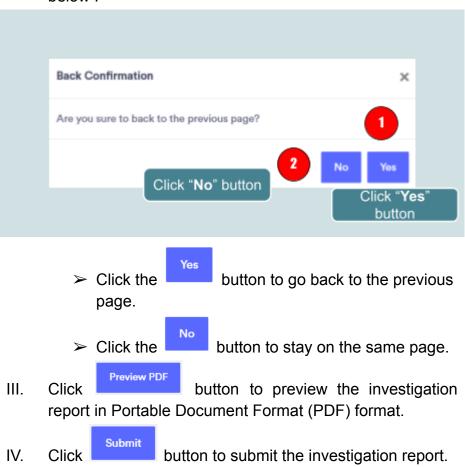
a. A part of the Edit Return From MDA page will be displayed as below :



- 1. Users can only update the information that has 'No' remark in this report.
- 2. Button Section
 - I. Button section will be displayed as below :



II. Click button to go back to the previous page and the confirmation pop-up message will be displayed as below :



3.8 DELETE MANDATORY PROBLEM REPORTING (MPR)

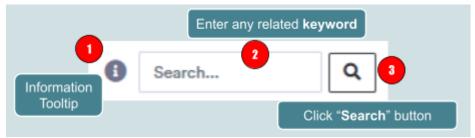
a. Click Delete button to delete the reporting and the pop-up will be displayed as below :

		Delete Fo	orm	Click "Delete" button
		Are you s	ure want to delete the form?	1
			Click "Cancel" button	Cancel Delete
1.	Click	Delete	button to delete the N	landatory Problem
		ng (MPF		
	•	U V	,	
2.	Click	Cancel	button to close the de	elete non-un
	0			note heb ab.

3.9 OVERDUE REPORTING TABLE

	Application Reporting	g Table		Over	due Reporting 1	fable (3)
			Ta	ble Filtering	6 Search	۰ ۹
NO.	MPR REFERENCE NO.	MEDICAL DEVICE NAME	DATE (DD/MM/YY)	DUE DATE (DD/MM/YY)	STATUS	ACTION
1	MDA/MPR /P0275-75615819-2022	MEDICAL TESTONA	22/02/2022	25/03/2022 Imost Overdue)	Almost Overdue	@ View @ Edit I≣ Log
2	MDA/MPR /P0274-95071273-2022		22/02/2022	24/03/2022	Almost Overdue	@ View @ Edit i≣ Log
3	MDA/MPR /P0272-21138592-2022	MEDICAL TEST011B	18/02/2022	20/03/2022	Overdue	Ø View Extend Date (0/2) I≡ Log

- a. The Overdue Reporting Table tabs page will be displayed as above:
 - 1. Table Filtering



I. Click (i) icon to get more information related to table filtering and the pop-up will be displayed as below :

		Information Click "X" button
		Searching Steps
		1. Type any keyword:- MPR Reference Number
		 Medical Device Name
		 Date (yyyy-mm-dd) (Eg: 2020-01-01)
		 Due Date (yyyy-mm-dd) (Eg: 2020-01-01)
		• Status
		2. Click the search icon button (Q) to find the report.
		Click "Close" button 2 Close
		Click × button or button to close the pop-up.
	П.	Enter any related keyword (based on information given).
	III.	Click 🖾 icon and the system will display the result.
2.	Action	Button for Almost Overdue Status
	I.	Click View button to view the investigation report that
		has been almost overdue. (Refer to 3.5.2 View
		Investigation Report)
	П	Click C ^{Edit} button to continue updating the

- II. Click button to continue updating the investigation report and submit the investigation report before overdue. (Refer to 3.7.2 Edit Investigation Report)
- III. Click button to view the investigation report log and the pop-up will be displayed as below :

NO.	DATE / TIME	STAGE	STATUS	USER
з	22/03/2022 08:31:52	Almost Overdue	Investigation report are Almost Overdue	System
2	22/02/2022 10:41:11	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST 0H
1	22/02/2022 10:40:23	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST 011

- 3. Action Button for Overdue Status
 - I. Click View button to view the investigation report that has been overdue. (Refer to 3.5.2 View Investigation Report)
 - II. Click Extend Date (0/2) button to request extension time and the pop-up will be displayed as below :

	Click "X" button
Do you need more exte	ontion time? (0/2) 1 ×
**REMINDER: Establishment one (1) application.	can request to extend the date up two (2) times only for
Request for extension	🔘 30 days
time:*	90 days
	120 days
	150 days
	180 days
Justification*	
Click	"Confirm" button 2 Confirm

- Click Confirm button to submit the request for extension time.
- \succ Click \times button to close the pop-up.
- III. Click button to view the investigation report log and the pop-up will be displayed as below :

NO.	DATE / TIME	STAGE	STATUS	USER
3	21/03/2022 08:51:33	Overdue	This report has exceeded the timeframe required	System
2	18/02/2022 11:44:21	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST 011
1	18/02/2022 11:42:06	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST 011
			Click "Close" button	Close

3.10 STATUS OF SUBMISSION INVESTIGATION

of Su	bmissions					
ist o	of Reporting				ible Filterii	ng
				2	Search	٩
NO.	DATE (DD/MM/YY)	MPR REFERENCE NO.	MEDICAL DEVICE NAME	LOCATION (INSIDE/OUTSIDE)	STATUS	ACTION
1	30/03/2022	MDA/MPR /P0306-22120695-2022	MEDICAL TESTOND	Outside Malaysia	Submitted	@ View I≣ Log
2	17/03/2022	MDA/MPR /P0354-59244598-2022	MEDICAL TESTOND	In Malaysia	Submitted	@ View I≣ Log
8	17/03/2022	MDA/MPR /P0311-91450907-2022	MEDICAL TESTOMB	In Malaysia	Submitted	@ View i≣ Log
4	16/03/2022	MDA/MPR /P0312-57933226-2022		Outside Malaysia	Submitted	Ø View i≣ Log

3.10.1 Status of Submission Reporting

- a. The Status of Submission Reporting page will be displayed as above :
 - 1. List of Reporting
 - I. List of Reporting will display the list that has been submitted by the user.
 - 2. Table Filtering



I. Click (icon to get more information related to table filtering and the pop-up will be displayed as below :

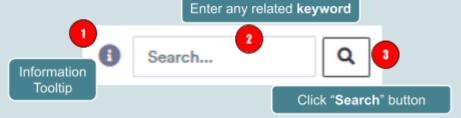
		Information Click "X" button
		Searching Steps
		Type any keyword:- MPR Reference Number
		 Date (yyyy-mm-dd) (Eg: 2020-01-01)
		 Medical Device Name Location (Inside / Outside)
		2. Click the search icon button (Q) to find the report.
		Click "Close" button 2 Close
		> Click × button or button to close the
	II.	pop-up. Enter any related keyword (based on information given).
	III.	Click icon and the system will display the result.
3.	Actio	n Button
-	I.	Click View button to view the submitted reporting and
		the view page. (Refer to 3.5.1 View Mandatory Problem Reporting)
	11.	Click IE Log button to view the reporting log and the pop-up will be displayed as below :
		Mandatory Problem Reporting (MPR) Log Click "X" button
		Application Log Details : MDA/MPR/P0306-22120595-2022
		NO. DATE / TIME STAGE STATUS USER
		2 30/03/2022 11:03:26 Submitted Submitted Mandatory Problem Reporting (MPR) report has been HOST submitted 011
		1 15/03/2022 1t:15:32 Draft Mandatory Problem Reporting (MPR) report has been HOST saved as draft Off
		Click "Close" button
		Click × button or button to close the pop-up.

	bmission	0	Investigat Cou	on Report nter					
Case Submission		Case Submission Under Processing				Total Case Running	Completed		
4			0		4		0		
NO.	DATE (DD/MM/YY)	MPR R	EFERENCE NO.	MEDICAL DEVI	CE NAME	LOCATION (INSIDE/OUTSIDE)	G Search.	ACTION	
1	17/03/2022	MDA/MPR/PI	0236-36966110-2022	MEDICAL TESTO	118	Outside Malaysia	Submitted	@ Vew ∐⊟ Log	
	17/03/2022	MDA/MPR/PI	0266-17793069-2022	MEDICAL TESTO	110	Outside Malaysia	Submitted	@ View [⊟ Log	
2				MEDICAL TESTO		In Malaysia	Submitted	@ View [⊟ Log	

3.10.2 Status of Submission Investigation

- a. The Status of Submission Investigation page will be displayed as above :
 - 1. Investigation Report Counter
 - I. There are four (4) types of reports counter will be displayed :
 - Case Submission : The total of investigation reports that have been submitted by the user.
 - Under Processing : The total of investigation reports that are in the process of evaluation by the Evaluation Officer.
 - Total Case Running : The combined total for Case Submission and Under Processing.
 - Completed : The total for the investigation report that has been approved by the Approval Officer.
 - 2. List of Final Report
 - I. List of Final Report will display the list that has been submitted by the user.

3.	Table Filtering	
		Enter any relat



I. Click (i) icon to get more information related to table filtering and the pop-up will be displayed as below :

Information Click "X" button
Searching Steps
 Type any keyword:- MPR Reference Number Date (yyyy-mm-dd) (Eg: 2020-01-01) Medical Device Name Location (Inside / Outside) Click the search icon button (Q) to find the report.
Click "Close" button 2 Close
Click × button or button to close the pop-up. Enter any related keyword (based on information given).

III. Click \bigcirc icon and the system will display the result.

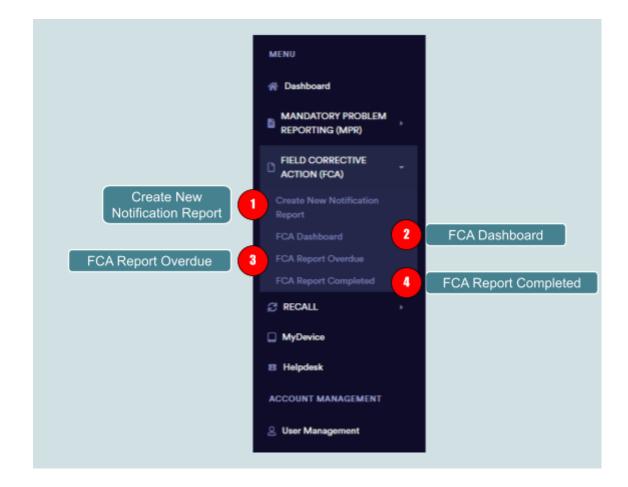
4. Action Button

- I. Click View button to view the completed and submitted investigation report (Refer to 3.5.2 View Investigation Report)
- II. Click **Log** button to view the investigation report log and the pop-up will be displayed as below :

NO.	DATE / TIME	STAGE	STATUS	USER
3	13/02/2022 21:03:37	Submitted	Investigation Report has been submitted	HOST OH
2	11/02/2022 21:49:49	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST 011
1	15/02/2022 08:21:39	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST OH
		C	Click "Close" button	Clo

4 FIELD CORRECTIVE ACTION (FCA)

4.1 FIELD CORRECTIVE ACTION (FCA) SIDEBAR



- a. Field Corrective Action (FCA) Sidebar will be displayed as above:
 - 1. Create New Notification Report
 - I. Create New Notification Report will display the create page for Notification report. (Refer to **4.3.1 Create New Notification Report**)
 - 2. FCA Dashboard
 - I. FCA Dashboard will display Field Corrective Action (FCA) main dashboard. (Refer to **4.2 FCA DASHBOARD**)
 - 3. FCA Report Overdue
 - I. FCA Report Overdue will display the list of FCA reports that are overdue. (Refer to **4.8 FCA REPORT OVERDUE**)

- 4. FCA Report Completed
 - I. FCA Report Completed will display the list of FCA reports that are completed. (Refer to **4.9 FCA REPORT COMPLETED**)

4.2 FCA DASHBOARD

	Corrective Action	FCAR	Report Counter					
	Notification Report		Follow Up Rep	ort		Closure	aport	
	Draft / Submitted	Return from MDA	Draft / Submitted	Return from MDA		raft / mitted		furn n MDA
	1	0	0	0		0		0
List o		List of FCA Re				4	Search	Filtering
No.	mer res.	Medical Device Name	Date FCA To Be Constraincated To User	Case Separation	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/P0000-83767737-2022	MEDICAL TESTORIA	Wes (14/03/2022)	24/03/2022	06/09/2022	Notification	Submitted	City of the second seco
Showin	p 1 of 1 emitties.							

- a. Field Corrective Action (FCA) Dashboard page will be displayed as above:
 - 1. FCA Report Counter.
 - 2. Click the Create New Notification Report button.
 - 3. List of FCA Report Table.
 - 4. Table Filtering.

4.2.1 FCA Report Counter

1 Notification R	eport Counter	2 Follow Up Re	p Report Counter			
Notificati	Notification Report		Follow Up Report		are Report	
Draft / Submitted	Return from MDA	Draft / Submitted	Return from MDA	Deaft / Submitted	Return from MDA	
1	0	0	0	0	0	
iotal FCA Report: 1	Total FCA Report					

- a. FCA have three (3) report counter that will be displayed as above:
 - 1. **Notification Report Counter** This counter displays the number of Notification reports with Draft/Submitted status and reports that are Returned From MDA.

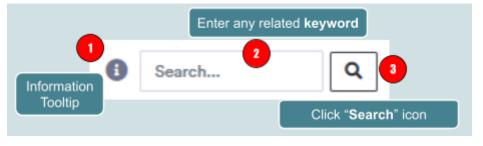
- 2. Follow Up Report Counter This counter displays the number of Follow Up reports with Draft/Submitted status and reports that are Returned From MDA.
- 3. **Closure Report Counter** This counter displays the number of Closure reports with Draft/Submitted status and reports that are Returned From MDA.
- 4. Total FCA Report.

Draft /

b. User can click on Submitted to view the list of all reports with Draft and Submitted status according to the report type. Table below shows the list for the Notification Report.

				Table Filt	ering 1	0 100	n. (
¥0.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Diatus	Action
,	MDA/FCA/P0000-63767757-2022	MEDICAL TESTOIDA	24/03/2022	06/09/2022	Notification	Submitted	Elvine (Bug (Folor 10 (Const
2	MDA/FCA/P0001-40294766-2022	MEDICAL TESTOIDA			Notification	Draft	Citylee Cityle Cityle Citylee Citylee
3	MDA/FCA/P0004-66035627-2022	MEDICAL TESTONA			Notification	Draft	Civies (ii).eg (ii) fait

a. Table Filtering shown as below:



I. User can click the ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information	×	
Searching Steps		
 Type any keyword:- FCA Reference Number 		
 FCA Report Type 		
 Medical Device Name Date Submission (yyyy-mm-dd) (Eg: 2020-0 	01-01)	
 Date Proposed Completion (yyyy-mm-dd) Status 	(Eg: 2020-01-01)	
2. Click the search icon button (Q,) to find the	report.	
	Close	
\succ Click the \times button	Close	button to alogo t
	OI	button to close t
pop-up.		
Enter any related keyword ((based on ir	nformation given)
Click the 🔍 icon and the		l display the resu
		i dieniav tha raeu

c. User can click on from MDA to view the list of all reports with Return from MDA status according to the report type. Table below shows the list for the Follow Up Report.

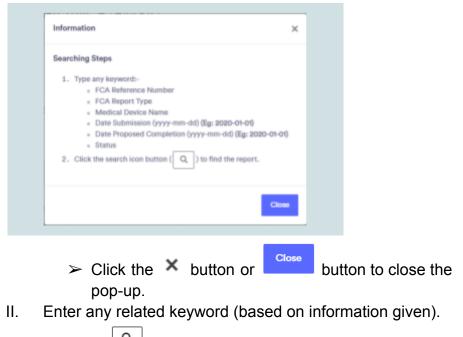
				Та	ble Filtering	1 • •	urch
6a.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/TCA/P0358-35674246-2022	MEDICAL TESTONA	25/03/2022	\$6/04/2022	Additional Follow Up	Return from MDA	China (ill.rg Chint interted
2	MDA/TCA/P0365-67482433-2022	MEDICAL TESTONB	96-03/2022	10/04/2022	Follow Up	Return from MDA	ØNew i⊒.ng Øticit Selected

1. Table Filtering shown as below:

Return

	Enter any relat	ted keyword
Information	Search ²	۹ 3
Tooltip	l	Click " Search " icon

I. User can click the *icon to get more information related to table filtering and the pop-up will be displayed as below:*



- III. Click the \bigcirc icon and the system will display the result.
- d. Total FCA report will display the sum of all numbers on the counter.

4.2.2 Create New Notification Report

a. Please refer to 4.3.1 Create New Notification Report.

4.2.3 List of FCA Report Table

a. List of FCA Report table will be shown as below:

					Table Filterin	ng 🔼 🙎	O Search.	. 0
No.	Ref No.	Medical Device Name	Date FCA To Be Communicated To User	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/PX0276- 44094838-2022	MEDICAL TESTONB				Notification	Draft	Cliview IBLog Clivie
2	MDA/FCA/P0370- 89395360-2022	MEDICAL TESTONB	Yes (28/03/2022)	06/04/2022	26/08/2022	Notification	Submitted	@View ill.og @Tollow Up
3	MDA/FCA/9X0366- 43263645-2022	MEDICAL TESTONB	Yes (05/03/2022)	\$4/03/2022	24/03/2022	Closure	Submitted	@View iB.og
4	MDA/FCA/P0366- 67482433-2022	MEDICAL TESTOHB	Yes (17/02/2022)	06/04/2022	10/04/2022	Action I Follow Up	Return from MDA	@View iB.og @Edit Selecte
5	MDA/TCA/P0363- 49523478-2022	MEDICAL TESTORIC	Yes (17/02/2022)	22/02/2022	31/03/2022	Closure	Submitted	@View IB.og

- The List of FCA Report table shows the list of all report types (Notification, Follow Up, Additional Follow Up, Closure) with Draft, Submitted, and Return from MDA status.
- 2. Table Filtering shown as below:



I. User can click the ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information	×		
Searching Steps			
 Type any keyword:- FCA Reference Number FCA Report Type Medical Device Name Date Submission (yyyy-mm-dd) (Eg: 2020-0 Date Proposed Completion (yyyy-mm-dd) (Eg: 2020-01-01)		
	Close		
Click the × button pop-up.	Or	button to clos	e the

- II. Enter any related keyword (based on information given).
- III. Click the \square icon and the system will display the result.
- 3. Action Button:
 - I. Click the View button to view the report. (Refer to 4.4.1 View Field Corrective Action (FCA) Report)
 - II. Click the button to view the reporting log and the pop-up will be displayed as below:

No.	Dete	Stage	Status	Officer
1	17/03/2022 14:54:50	Draft	MDA/MPR/P03H-91450907-2022 opened a new Field Corrective Action (FCA) application. The overdue date is 16/704/2022	HOST 011
				_

- III. Click the Follow Up button to create a new Follow Up report. (Refer to 4.3.2 Create New Follow Up Report)
- IV. Click the **i** Additional Follow Up button to create a new Additional Follow Up report. (Refer to 4.3.3 Create New Additional Follow Up Report)
- V. Click the Closure button to create a new Closure report. (Refer to 4.3.4 Create New Closure Report)
- VI. Click the **Edit** button to update the Notification report. (Refer to **4.6.1 Edit Notification Report**)
- VII. Click the Click the VID button to update the Follow Up report. (Refer to 4.6.2 Edit Follow Up Report)
- VIII. Click the **Content** button to update the Return from MDA report. (Refer to **4.6.3 Edit Return from MDA Report**)
 - IX. Click the Delete button to delete the Notification report. (Refer to 4.7.1 Delete Notification Report)
 - X. Click the Delete Follow Up button to delete the Follow Up report. (Refer to 4.7.2 Delete Follow Up Report)

4.2.4 Table Filtering

a. Table Filtering will be shown as below:



I. User can click the ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information	×	
Searching Steps		
 Type any keyword:- FCA Reference Number FCA Report Type Medical Device Name Date Submission (yyyy-mm-dd) (Eg: 2020-01-01) Date Proposed Completion (yyyy-mm-dd) (Eg: 2 Status Click the search icon button (Q) to find the report 	020-01-01)	
\succ Click the $ imes$ button or	Close	button to close th
pop-up.		
Enter any related keyword (ba	ised on i	information given).

III. Click the \bigcirc icon and the system will display the result.

4.3 CREATE REPORTING

4.3.1 Create New Notification Report

Field Corrective Actio	n	
FGA.Swithouril > FGA.Notification		
	MEDICAL DEVICE	FIELD CORRECTIVE ACTION REPORT
(*)-required		
This page DOES NOT HAVE AN AUTO	SAVE FUNCTION./Tease use the BACK BUTTON at the	a bottom of the page and click the SAVE AS DRAFT in the confirmation box.
FGA Beference No.	MDA/FCA/P0001-69670519-2022	FCA Reference Number
 Section A : Field Corrective A 		
 Section A (Field Centerby) A 	tion Report	Section A: Field Corrective Action Report
 Section 8 : Establishment Part 	icular 3	Section B: Establishment Particular
	Device Details	
 Section C : Affected Medical I 	Device Details	Section C: Affected Medical Device Details
 Section D : FCA Proposed Plan 	and Action 5	Section D: FCA Proposed Plan and Action
 Section E : FCA Information 	6	Section E: FCA Information
 Section F : Follow Up (Dnly op 	ened in Follow Up Report)	Section F: Follow Up
 Section G : Closure Information 	n Report (Only opened in Closure Report)	Section G: Closure Information Report
 Section H : Others Information 		Section H: Others Information
Declaration 10	Declaration	
· · · ·		
		/ are correct, completed and current to this date.*
 I understand and acknowledge 	that is an otherce under section 76 of Act 737, to	make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*
Person Responsible	iman Afrijah Birti Azman	
for the Establishment		
Jub Title	MANAGER	
Telephone	603-96541267	
	and defined one	
Ernal Address	pmev.dev@gmail.com	11 Button Section
		Back Clear Provide FCF Submit Notification
		Back Cheer Providee PDF Subret NeteRealizer
		Back Clear Provine PCF Subrel Notification
		Dack Chair Province PDF Subset NotPhaten

- a. Creating New Notification report will be display as above:
 - 1. FCA Reference Number.
 - I. FCA Reference Number is auto-generated by the system.
 - 2. Section A: Field Corrective Action Report.
 - I. Section A will be display as below:

Type of Report	Notification Follow Up Closure
1. Title of FCA*	
2. Type of Field Corrective Action (FCA)*	 Return Modification Exchange Specific Advice Destruction

- II. User are required to fill in all fields that marked with an asterisk (*).
- 3. Section B: Establishment Particular.
 - I. Section B will be display as below:

1. Name of Company	Medical Device Authority Development Team (ICT)	
2. Company Address	26 JALAN PRIMA 9	
		é
3. Contact Person Name	Azzannie Firdaus Bin Azali	
4. Job Title	MANAGER	
5. Telephone Number	603-96541267	
6. Email Address	unijayatest01@nada.email	

- II. All information in this section will be auto-filled by the system.
- 4. Section C: Affected Medical Device Details.
 - I. Section C will be display as below:

Medical Device Authority Ministry of Health Malaysia

1. Medical Device Name •				
	Select Medical Device Name			
		-		
	Please choose one of the options			
2. MDA Registration				
Number				
3. Device intended use				
2. Dental Interded day				
		4		
4. Device Classification				
A. DEVICE CONSTRUCTION				
5. Device Risk Type				
6. Medical Device				
Category				
7. GMDN				
7.1 List of GMDN	Select GMDN +			
	Please choose one of the options		_	
	Table of Affected D	enice Details*		
	(Establishment may download the template excel			
	1. Example: Drample for Table of Affect			
	2. Template: 🖥 Template for Table of Affect	ted Device Details (PCA) als 📥		
	Serial Numb	er / UDI Code		
No. Product	/ Catalogue / Identifier Number (If app	er / UDI Code slicable) Batch Number	Lot Number Quantity	
	No affected device det	ails to be display.		
		and to be angled		
			Total O	
			Add Details of Affected Devices	
9. Accessories /				
Associated medical				
Associated medical devices affected				
devices affected				
devices affected				
dovices affected (if any)				
dovices affected (if any)			_	
devices affected (if any) 10. Manufacturer name			•	
devices affected (if any) 10. Manufacturer nome 11. Manufacturer			8	
devices affected (if any) 10. Manufacturer nome 11. Manufacturer			•	
devices affected (if any) 10. Manufacturer nome 11. Manufacturer			8	
dovices affected (if any) 10. Manufacturer name 11. Manufacturer address			•	
dovices affected (if any) 10. Manufacturor name 11. Monufacturer address 12. AR Name*				
dovices affected (if any) 10. Manufacturer name 11. Manufacturer address			8	
dovices affected (if any) 10. Manufacturor name 11. Manufacturor address 12. Ail: Name*			8	
dovices affected (if any) 10. Manufacturor name 11. Manufacturor address 12. Ail: Name*				
dovices affected (if any) 10. Manufacturor name 11. Manufacturer address 12. AR Name 13. Distributor Name				
dovices affected (if any) 10. Manufacturor name 11. Monufacturer address 12. AR Name*				
dordoss affectad (if any) 10. Manufacturor namo 11. Manufacturor address 12. AR Namo 13. Distributor Name			2	
dordoss affectad (if any) 10. Manufacturor namo 11. Manufacturor address 12. AR Namo 13. Distributor Name			2	
dovices affected (if any) 10. Manufacturor name 11. Manufacturer address 12. AR Name 13. Distributor Name 14. Importer Name				
dovices affected (if any) 10. Manufacturer name 11. Manufacturer address 12. AR Name 13. Distribunor Name				

- User are required to fill in all fields that marked with an asterisk (*).
- III. Click the dropdown button to choose one Medical Device Name for Question 1.
- IV. All questions will be automatically filled by the system according to the Medical Device Name that the user chose except for Question 7.1, 9, 12, 13, 14, and Table of Affected Device Details.
- V. Table of Affected Device Details Section

 \succ

1 Affected Device De	etails Section			
	Table of Affected Device Details*			
	nent may download the template excel file & upload at given complet D Example for Table of Affected Device Details (FC mplate: Template for Table of Affected Device Details (FC	📥 elz. (A		
Template for Table of Affec Device Details	Serial Number / UDI Code (if applicable) No affected device details to be display	Batch Number	Lot Number	Quantity
			Total	0
	Click "Add Details of Affe Devices" button	cted 3	Add Details of A	Miscled Devices

- Table of Affected Device Details will be displayed as above.
- There are two (2) template for Table of Affected Device Details that user can download which are:
 - Example for Table of Affected Device Details
 - Template for Table of Affected Device Details
- Users are required to use the template provided to upload it in the table.

Add Details of Affected Devices button will be enabled after the user fills in the Medical Device Name in Question 1.

By clicking Add Details of Affected Devices button, the system will display Details of Affected Devices page shown as below:

		3
invice details:		Action Button
No. Prod Uploaded File Section Serial Number / UDI Code Betch Number Lot Number	Quantity	Action
1. Example Example 12346678 12346678	100	(2 Eds 2 Delete
Total	100	

In the Upload File Section, users can choose the file that needs to be uploaded by clicking Choose File button and

needs to be uploaded by clicking Choose File button and



button will be enabled after the user chooses

the file. Then click button to import the file in the table.

- In the Uploaded File Section, it will display the file that the user uploads.
- In the Action column, it has two (2) button that user can use:
 - User can click CE Edit button to update the affected devices details in the table and the system will display the popup to update the details of affected devices shown as below:

Update det	ails of affected devices ×
Product / C	Catalogue / Model Number:
Example	
Serial Num	ber / UDI Code
Example	
Batch Num	ber
12345678	
Lot Numbe	e de la companya de la
12345678	Click "Update"
Quantity:	button
100	2
	"Clear" button
	 Click the button to clear all the information.
	 Click the Update button to update the information.
0	User can click the Delete button to delete the

	Delete Form Click "Delete" button
	Are you sure want to delete? 2
	Click "Cancel" 1 Cancel Delete
	I. Click the cancel button to go back to the previous page.
	II. Click the button to delete the affected device details.
	Click the Next button to continue to the next question in section C.
5.	Section D: FCA Proposed Plan and Action. I. Section D will be display as below:

as This is summary information of the FCA planned by the establishment. If you have documents related to this action planned, please splead it in section H of this from.

- II. User are required to fill in all fields that marked with an asterisk (*).
- 6. Section E: FCA Information.
 - I. Section E will be displayed as below:

** This information is generated as "The" and	nativally if hand on the 13						the state
1. Did the FCA arise	O Tex						
due to an incident?*	O No						
2. Did this incident occur in Malaysia?*	O Yes						
outer at waterpost.	O No						
5. If yos, has the	() Tes						
incident been reported	O No						
to MDAP*							
4. Evaluation of the risk							
associated with affected							
medical device (Health Hazard Evaluation							
Report) ()	Choose Eller	No file choses					
	Re-upland films with 4	alate al generate lites.	The test file selected and				
	Maligia dia spical s	IN COMPACTOR THE INCOME OF	- I'be this fire approached appro-	ar some 2018			
5. Background							
Information and reason for the FCA?*							
NAME AND PARTY.							
6. Root Cause*							_
							10 A
	** The cost owner in face	el co vitat is initial cases the cos	on to instant the PCA. Totally	Record same is the first balances over	diverse in tables.		
2. FCA plan and action to be taken							
(corrective action)*							
a behing on antiput to							
8. Advice on actions to be taken by the							
distributor and the user*							
9. Number and name of							
		replate for Name of Affect	and Consigning the A				
affected units supplied		nglate for Name of Affect	od Consigned star 🛓				
affected units supplied		nglate for Name of Affect	od Consignos, stor 🛓				
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affected units supplied	Choose Ries		official fields	of accused 2018). Vill In geneticy and Sen			
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affacted with supplied to each consigner.	Choose Ries	No file chosen	official fields	nt annal 2005. Nil to quarty will fan.			
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affected units applied to each consigner* 10. Has the FCA been communicated to all	Choose Rise To-spiced files will of Mithigh (Ex-spiced ar- "Pena-spiced ar- "Pena-spiced ar- "Pena-spiced ar- Data-spiced ar- dol/mon/yy No	Sio file chosen blex of proving file. In closed for the second rule lenges of the second blead lenges of the second blead	a d'ha shel bia qirabel met	nt monal 2028. ville is quality and law.			
affected units applied to each consigner*	Choose Rise Resolution of the off of things for synch or Place spind or Ves Data sent: dd/mm/tys No Expected d	No file straven Man of any straven file. In the straven file to be seenen to former for sease adment former for sease adment 197	n file net file special ser n files d'Almi respec	nt monel 2028. vili is quality and law.			
affected units applied to each consigner*	Choose Rise To-spiced files will of Mithigh (Ex-spiced ar- "Pena-spiced ar- "Pena-spiced ar- "Pena-spiced ar- Data-spiced ar- dol/mon/yy No	No file straven Man of any straven file. In the straven file to be seenen to former for sease adment former for sease adment 197	a d'ha shel bia qirabel met	nt monal ISBS. vik is quality and law.			
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affected units applied to each consigner" ① 10. Has the FCA bees conservation to the all consignees " 11. No. of affected units and the p 11.1 Menufactured in Melopsia" 11.2 Imported into Melopsia" 11.3 Supplied in Melopsia" 11.4 Expected abipment to Malaysia" 11.0 Date of commencement of FCA, by resenfacture" 11. Date of	Choose File Respect fees to 1 they for up to 2 ** Passes Date seets dd/mm/yp No Expected dd dd/mm/yp seried that affected	No file chooses deb discusses file deb discusses file between the base setting of the set of the set of the setting of the setting of the setting of the Galaxies of the setting file of t	e drike wed file, global men in drawn of default images / kraparted / supplied in Incard (Supers)	Maloysia:* Fice (speer dd/mm/yyy dd/mm/yyy		44/mm/9999	0
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- II. Users are required to fill in all fields that marked with an asterisk (*).
- III. User can click the ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

1. Click "Browse" 2. Multiple files upload	f are allowed but need to	be upload at th	o sarso tirso she	wn as below.		
Example:						
 Example 1 Example 3 						
 Exomplo 7 						
Ciper.	+ thirt - bourhads			h Dorohoadh	×	
Organiza +	New Julies		6 / Sec	R + 11	•	
ConeDalase						
This PC	PDF	PDF	PDF			
E Deuktop		Barrale 2	Darryle 1			
S Douries						
Music Michael						
Fideor 5 (05) 105	PDF	PDF	PDF	PDF		
- DAM (D)	Ecorgie 4	Example 5	Ecomple 6	Ecomple 7		
	Hanama Hample? Tex	mple I' 'Example 3'	v Al Plan		*	
			Dyes	Cancel		
 Re-upload files will a The input field will a 		uninaded (Faur	unior 3 films solve	teril.		
4. 110 890, 180 988 9	tax non many mer and	operates (Care	speer o const perce	10000		
					_	
					Clea	
	Close					

- 7. Section F: Follow Up.
 - I. The Follow Up section will only be opened in the Follow Up Report.
- 8. Section G: Closure Information Report.
 - I. The Closure section will only be opened in the Closure Report.
- 9. Section H: Others Information.
 - I. Section H will be displayed as below:

1. Copy of official manufacturer Field Safety Notice (FSN)* (Choose Files No file chosen Re-spload file will delete all previous files. Multiple file upload are allowed but the maximum size of the total files uploaded must not enceed 200/B.	
2. Other supporting documents	Choose Files No file chosen Re-upload file will delete all previous files. Maltiple file upload are allowed but the maximum size of the total files uploaded must not enceed 200/IB.	
3. Remark		

- Users are required to fill in all fields that marked with an asterisk (*).
- III. User can click the ⁽¹⁾ button to get more information about multiple file upload. The pop-up will be displayed as below:

 Click "Browse" Multiple files u 	pload are allow	ved but need to I	be upload at the	sarso tirso sh	own as below.			
Example: • Example • Example • Example • Example	8					×		
	• • • • •	PC > Downloads	÷	0 P 10	ch Downloads			
	divine * FC Colopents exhibut summarile balt	PDF Example 1	PDF Barryle 2 (12)	PDF Isospie 1		•		
■ * L 0	6 (C) AMA (D) v	PDF Grangle 4	PDF Example 5 git 11 'Example 3'	PDF Example 6 will Palm Dyn	PDF Grangels 7			
 Re-upload file The input field 			picaded (Exar	pla: 3 filos solo	cted)			
							Gas	
	the	Close		tton t				

10. Declaration.

I. The Declaration section will be displayed as below:

Declaration		
I hereby attest that the informat	tion and attachment provided on this reporting is / are correct, completed and current to this date.*	
I understand and acknowledge	that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue,	, inaccurate or misleading.*
Person Responsible	Iman Adigah Binti Azman	
for the Establishment		
Job Title	MANAGER	
Telephone	603-96541267	
Email Address	priox.dev@gmail.com	

- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - ➤ Name of Reporting Person
 - ➤ Job Title
 - ≻ Telephone
 - ➤ Email Address
- 11. Button Section.
 - I. This section displays all buttons in the Notification Report.

Back	Clear	Preview PDF	Submit Notification
_	_		

II. Click button to go back to the previous page. There will be two (2) types of pop-up that will be displayed as below:

1 Back Confirmation Pop-up	
Back Confirmation	Click "Yes" button
Are you sure to go back to the previous page?	2
Click "No" 3	o Yes

➤ Back Confirmation Pop-up.

- If the question Table of Affected Device Details in Section C has been filled, this Back Confirmation pop-up will be displayed.
- Click the ^{Yes} button to go back to the next page.
- Click the button to stay on the same page.



Draft Confirmation Pop-up

- If the question Table of Affected Device Details in Section C has not been filled, this Draft Confirmation pop-up will be displayed.
- Click the Save as Draft button to save the report as draft.
- Click the [№] button to delete the report.
- III. Click the button to clear all the information in the report except the default value. The pop-up will be displayed as below:

1 Clear Confirmation Pop-up	
Clear Confirmation	Click *Clear * button
Are you sure want to clear all information?	2
Click "No" 3 button	No
Clear Confirmation Pop-up	p.
 Click the clear bu information. 	utton to clear all the
○ Click the but	tton to stay on the same
Click the Preview PDF button to vie Document Format (PDF) format. (Field Corrective Action (FCA) R	•
 Click the Submit Notification button to report. This button will be enabled in the Declaration section.	to submit the Notificatic d if the user tick the che

4.3.2 Create New Follow Up Report

Field Corrective Action					
Main Dashboard > FCA Dashboard > FCA Follow Up					
This page HAS AN AUTO SAVE FUNCTION. Your form would be saved automatically as you make progress on the browser. Please be cautious with your case details.					
Notification Section Field Corrective Action (FCA) Report Follow Up Form					
Section A: Field Corrective Action Report					
1. MDA FCA Reference Number	MDA/FCA/PX0345-79741604-2022				
1.1 MDA MPR Reference Number	MDA/MPR/P0235-48710369-2022				
2. Type of Report	Notification				
3. Title of FCA	etret				
4. Type of Field Corrective Action (FCA)	Return				
Section B : Establishment Particulars					
1. Name of Company	Medical Device Authority Development Team (ICT)				
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA				
3. Contact Person Name	HOST 011				
4. Job Title	MANAGER				
Section F: Follow Up Section F: Follow Up					
Section G: Closure Information Report (Day opened in Closure Report)					
Section H: Others Information					
Declaration 5 Declaration					
I hereby attest that the information and attachment	provided on this reporting is / are correct, completed and current to this date.*				
I understand and asknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or mideading.*					
Person Responsible Irran Afigah Binti / for the Establishment	uman				
Job Title MANAGER					
Telephone 603-96641267					
Email Address providev@grad.c	6 Button Section				
	Back Class Preview PDF Subset Follow Up				

- a. Creating New Follow Up report will be display as above:
 - 1. Notification Section.
 - I. Users can view the Notification section in this Follow Up report.
 - 2. Section F: Follow Up.
 - I. Section F will be display as below:

1, Follow Up (Progress of FCA, together with reconcellation status and/or effectiveness check and its method)* 2. Has the FCA able to completed withis the proposed timeline/*	✓ Section F : Follow Up	
	of FCA, together with reconclisation status and/or affectiveness check and its method)* 2. Has the FCA able to completed within	

- II. User are required to fill in all fields that marked with an asterisk (*).
- 3. Section G: Closure Information Report.
 - I. The Closure section will only be opened in the Closure Report.
- 4. Section H: Others Information.
 - I. Section H will be display as below:

 Section H : Others Inform 	writion	
1. Copy of official matufacturer Field Safety Notice (FSN)	Choose Files No file chosen Ke galad Sax val Sains al person Sax. Sobgle for glad are slowed by the assess rise of the total film splanded mart out exceel 2008. • TEMPLATE (MDA_FCA_P0370_B0395360_2022) (MHLQaHa).pdf	
2. Other supporting documents	Choose Files No file choose Registed Saw roll Meter all protons time. Subply for grant an elevent of the sectorum rise of the total files uplanded must not encoded 200-20.	
3. Remark		

- II. Users can update the information in this section.
- III. User can click the ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

 Click "Browse" Multiple files upload 	are allowed but need to be uploa	d at the same time sh	own as below.		
Example: • Example 1 • Example 3 • Example 7 © Open				×	
	+ thirFC > Downloads	+ 0 P In	ch Downhoads		
Organica * Conglicita The PC III Original Decimana			#+ B (
 Pictures Mideot O6 (C) DAM (D) 	PDF PD Garget Garget P	nes Exampled	PDF Garge P		
 Re-upload files will de The input field will st 	where all previous files. the how many files user uploaded	f (Example: 3 files sole			
				Close	
	Close				

5. Declaration.

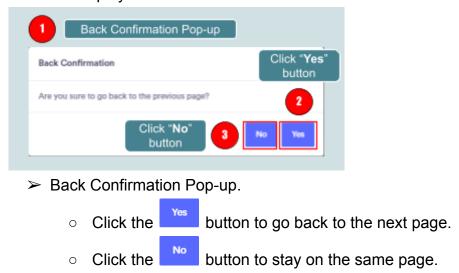
I. The Declaration section will be display as below:

Declaration						
I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*						
I understand and acknowledge t	that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccur	rate or misleading.*				
Person Responsible for the Establishment	Iman Afiqah Binti Azman					
for the Establishment						
Job Title	MANAGER					
Telephone	603-96641267					
Email Address	priezdev@gmail.com					

- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - Name of Reporting Person
 - ➤ Job Title
 - ≻ Telephone
 - ➤ Email Address
- 6. Button Section.
 - I. This section displays all buttons in the Follow Up Report.

Back Clear Preview PDF Submit Follow Up	_			
	Back	Clear	Preview PDF	Submit Follow Up

II. Click button to go back to the previous page. The pop-up that will be displayed as below:



III. Click the clear button to clear all the information in the report except the default value. The pop-up will be displayed as below:

	1 Clear Confirmation Pop-up
	Clear Confirmation Click *Clear" button
	Are you sure want to clear all information?
	Click "No" 3 No Clear
	 Clear Confirmation Pop-up.
	 Click the button to clear all the information.
	 Click the button to stay on the same page.
IV.	Click the Preview PDF button to view the report in Portable Document Format (PDF) format. (Refer to 4.5.1 Preview PDF Field Corrective Action (FCA) Report)
V.	Click the Submit Follow Up button to submit the Follow Up report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.3.3 Create New Additional Follow Up Report

Field Corrective Ac	Field Corrective Action					
Main Dashboard + FCA Dashboard + FCA Follow Up						
This page DOES NOT HAVE AN A	AUTO SAVE FUNCTION.					
	_					
Notificat Sectio	1 Correc	tive Action (FCA) Report Additional Follow Up Form				
Section A: Field Correct	ive Action Report					
1. MDA FCA Reference M	Number	MDA/FCA/P0356-99616777-2022				
2. Type of Report		Follow Up				
3. Title of FCA		Lorem lpsum is simply dummy text of the printing and typesetting industry.				
4. Type of Field Correcti	ive Action (FCA)	Exchange				
Section B : Establishmen	nt Particulars					
1. Name of Company		Medical Device Authority Development Team (ICT)				
2. Company Address		011, JALAN CYBERIA 1, CYBERJAYA				
3. Contact Person Name		HOST OM				
4. Job Title		MANAGER				
5. Telephone Number		0123456789				
 Additional Follow Up 	Additional Follow Up Section Additional Follow Up					
 Section G : Closure Infor 	 Section G: Cloure Information Report (Driv operad in Cloure Report) 3 Section G: Closure Information Report 					
 Additional Others Inform 	Additional Others Information					
Declaration 5	Declaratio	on				
I hereby attest that the inf		tt provided on this reporting is / are correct, completed and current to this date.*				
I understand and acknowle	ledge that is an offence u	inder Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or				
misleading.*						
Person Responsible	HOST 011					
for the Establishment						
Job Title	MANAGER					
Telephone	0123456799					
Email Address	host011@sebumbung.c	6 Button Section				
		Buck Cheer Submit Additional Follow Up				

- a. Creating New Additional Follow Up report will be display as above:
 - 1. Notification Section.
 - I. Users can view the Notification section in this Additional Follow Up report.
 - 2. Section Additional Follow Up.
 - I. Section Additional Follow Up will be displayed as below:

 Additional Follow Up 	
1. Follow Up (Progress of FCA, sogether with reconciliation status and / or effectiveness check	
and its method)* 2. Has the FCA able to completed within the proposed timeline?*	○ Yes ○ No dd/mm/yyyy

- Users are required to fill in all fields that marked with an asterisk (*).
- 3. Section G: Closure Information Report.
 - I. The Closure section will only be opened in the Closure Report.
- 4. Section Additional Others Information.
 - I. Section Additional Others Information will be display as below:

 Additional Others Inform 	rtion	
1. Copy of official manufacturer Field Safety Notice (FSN)	Chaoses Files: No file chosen Mo-spisal tites will delete all pervises tites. Multiple file spisal are allowed but for maximum size of the total Elex spisaled must not exceed 2004B.	
2. Manufacturer / Local Authorized Representative Field Safety Norice (FSN), List Affected Customer/User, or Others information	Choose Files No file chosen Re-spice files not deter at process line. Mathyle file spiced are allowed but the maximum size of the total files spiceded must not exceed 200/B.	
3. Remark	Enter any remark	

- II. Users can fill in this section if needed.
- III. User can click the ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

1. Click "Browne"					
2. Multiple files upload are allowed bu	I need to be upload at the	same time shown	as below.		
Example: • Example 1					
 Exemple 3 					
 Example 7 				-	
Cyser-			×		
	witadi v	0 P See 0	turnhadh		
Organiza + Max-falder			× · · •		
 OneDelue 					
II Chipsés	DF PDF	PDF			
Deutiop Decumaria	rgir 1 Buangin 2	Example 1			
Sector Earlie	this week (13)				
Music Richards					
Tideos P	DF PDF	PDF	PDF		
05 (C) DAM (D) Exe	ngilo 4 Example 5	Example 6	Ecomple 7		
W III III III III III III III III III I	ngie 7 'Transpie 1' Transpie 7'	v Al Pier	_	1	
	del carde carde c	Open	Cancel		
3. Re-upload files will delete all previo					
4. The input field will state how many	ties user uploaded (Exam	ple: 3 lites selecte	-0		
				Close	
	Close				
Click the	la			ack to th	

5. Declaration.

I. The Declaration section will be display as below:

Declaration						
Ihereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*						
 I understand and acknowledge t 	hat is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*					
Person Responsible for the Establishment	Iman Afiqah Binti Arman					
Job Title	MANAGER					
Telephone	603-96541267					
	pmax.dev@pmail.com					
Email Address	princongenia.com					

- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - Name of Reporting Person
 - ➤ Job Title
 - ➤ Telephone
 - ➤ Email Address
- 6. Button Section.
 - I. This section displays all buttons in the Additional Follow Up Report.

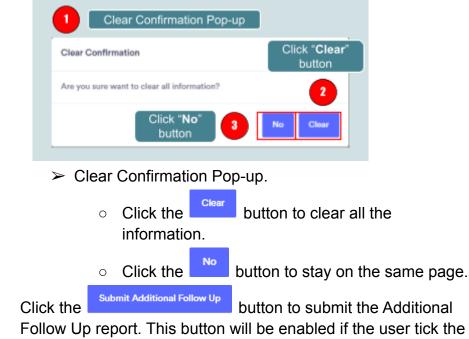
IV.

|--|

II. Click button to go back to the previous page. The pop-up that will be displayed as below:

0	Back Confirmation F	Pop-up		
Back Confi	irmation		Click "Yes" button	
Are you sur	e to go back to the previous	page?	2	
	Click "No button	2" 3 🔤	Yes	
≻ Back	c Confirmation	Pop-up.		
0	Click the		go back to	the nex
0	Click the	button to	stay on the	e same p

III. Click the button to clear all the information in the report except the default value. The pop-up will be displayed as below:



Follow Up report. This button will be enabled if the user tick t checkbox in the Declaration section.

4.3.4 Create New Closure Report

Field Corrective Act	tion	
Main Dashboard > FGA Dashboard >	FCA Closure	
This page HAS AN AUTO SAVE FU	NCTION. Your form would	be saved automatically as you make progress on the browses. Please be cautious with your case details.
1 Notification	EIGIO (Corrective Action (FCA) Report Closure Form
Section A: Field Corrective	re Action Report Form	
1. MDA FCA Reference No	umber	MDA/FCA/PX0346-79741604-2022
1.1 MDA MPR Reference N	lumber	MDA/MPR/P0235-48710369-2022
2. Type of Report		Notification
3. Type of Field Corrective	e Action (FCA)	otret
4. Type of Field Correctiv	e Action (FCA)	Return
Section B : Establishment	Particulars	
1. Name of Company		Medical Device Authority Development Team (ICT)
2. Company Address		Off, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name		HOST ON
4. Job Title		MANAGER
 Section G : Closure Inform Section H : Others Inform 		Section G: Closure Information Report Section H: Others Information
Declaration 4	Declaratio	n
 I hereby attest that the info 	ormation and attachmen	t provided on this reporting is / are correct, completed and current to this date.*
 I understand and acknowle misleading.* 	idge that is an offence u	nder Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or
Person Responsible	HOST 0H	
for the Establishment		
Job Title	MANAGER	
Telephone	0123456789	
Email Address	host011@sebumbung.c	om 5 Button Section
		Back Cheer Subtrit Closure

- a. Creating New Closure report will be displayed as above:
 - 1. Notification Section.
 - I. Users can view the Notification section in this Follow Up report.
 - 2. Section G: Closure Information Report.
 - I. Section G will be displayed as below:

✓ Section G : Closure Information Report					
1. Status completion FCA of each affected medical device*	Enter any remark				
2. Copy of acknowledgement receipt by the affected users on completion of the FCA*	Choose Files No file choosen Requisal Devid dete al prevan Des. Matgie Be opleal an allowed but Be maximum size of the total Bin opleaded must not exceed 2048.				
3. Proposed action to prevent recurrence of the problem (Preventive Action)*	Enter any remark				

- II. Users are required to fill in all fields that marked with an asterisk (*).
- III. User can click the ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

Example 3 Example 7		· Downloads		b D fee	h Downloads	×		
	the faller	Downloads		0 /* See	R · D			
Constitue	*					-		
The PC		_	-	_				
2 10 Objecto		PDF	PDF	PDF				
E Deumani		Example 1	Buample 2	Example 1				
4 Download	· ·	Earlier this week	k (93)					
Music								
Videos		PDF	PDF	PDF	PDF			
5 05 (C)		POP	POP	POP	POP			
- DAMA (D)		Ecomple-4	Example 5	Example 6	Ecomple 7			
				1.00000				
	The name	(Dendric 2. Den	mple 11 'Example 31	- All Prim	Cancel	-		
iced files will d put field will st			upiteded (Exam	rple: 3 files sole	red)		Ocer	

- 3. Section H: Others Information.
 - I. Section H will be displayed as below:

Copy of official	Choose Files No file chosen	
nanufacturer Field Safety lotice (FSN) 🚺	He optical films will delate all province files. Multiple file uplead are allowed but the maximum size of the total files upleaded must not exceed 2004B.	
	 TEMPLATE (MDA_FCA_P0370_89395360_2022) (kHLQuHe).pdf 	
. Other supporting ocurrents	Choose Files No file chosen To splead the vell blets all provide file.	
	Multiple file spinal are allowed but the maximum size of the total files upleaded must not exceed 2054B.	
Remark		

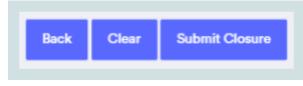
- II. Users can update the information in this section.
- III. User can click the ¹ button to get more information about multiple file upload. The pop-up will be displayed as below:

 Example Example Open 	7					×		
Oqueta		> Downloads		6 /2 See	E · I	•		
. One	014					~		
💷 Tea		and the second	0.00			1		
3 10	1 Clajente rubban	PDF	PDF	PDF				
	cumarite	Example 1	Baample 2	Example 1				
4 De	panloads -	Carlier this week	(13)					
3 M								
and Po			and the second second		and the second second			
E 10		PDF	PDF	PDF	PDF			
	MA IDU	Ecomple-4	Example 5	Example 6	Ecomple 7			
-	*					~		
	Fixeara	"bangic 7. 'Con	npis I'' Example 3'	 All Plan Open 	Carson			
 Re-upload files The input field 			uploaded (Exam	pla: 3 files selec	ted)			
							Close	

- 4. Declaration.
 - I. The Declaration section will be display as below:

Declaration	
Thereby attest that the informat	ion and attachment provided on this reporting is / are correct, completed and current to this date.*
I understand and acknowledge	that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*
Person Responsible	Iman Afigah Titnii Azman
for the Establishment	
Job Title	MANAGER
Telephone	603-96641267
Email Address	pmsv.dev@gmail.com

- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will displayed person responsible details which are:
 - > Name of Reporting Person
 - ➤ Job Title
 - ➤ Telephone
 - ➤ Email Address
- 5. Button Section.
 - I. This section displays all buttons in the Follow Up Report.



II. Click button to go back to the previous page. The pop-up that will be displayed as below:

Back Confirmation Pop-up	
Back Confirmation	Click *Yes" button
Are you sure to go back to the previous page?	2
Click "No" 3	No Yes

Back Confirmation Pop-up.

0

- Click the ^{Yes} button to go back to the next page.
 - Click the button to stay on the same page.
- III. Click the button to clear all the information in the report except the default value. The pop-up will be displayed as below:



➤ Clear Confirmation Pop-up.

- Click the clear button to clear all the information.
- \circ Click the button to stay on the same page.
- IV. Click the Submit Closure button to submit the Closure report. This button will be enabled if the user tick the checkbox in the

Declaration section.

4.4 VIEW REPORTING

4.4.1 View Field Corrective Action (FCA) Report

a. Click the **View** button to view the reporting and a part of the view page will be shown as below:

Field Corrective Action	
Main Daubheard > FGA Dashheard > View Report	
1 View Report Field Corrective	e Action Report
Section A: Field Corrective Action Report 1. MDA FGA Reference Number	MDA/FCA/P0229-96266492-2021
2. Type of Report	Closure
3. Title of FCA	borang 10tt
4. Type of Field Corrective Action (FCA)	Destruction
Section B : Establishment Particulars	
1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 0H
4. Job Title	MANAGER
5. Telephone Number	0123456709
6. Email address	host0110sebumbung.com
Declaration	
	Person Responsible for the Establishment: HOST 011
	Job Title: MANAGER
1. Reporting Person	Telephone Number: 0122456789 PDF" button
	Email Address: host011@sebumburg.com
	Click "Back" button 3 Back Provine PDE

- 1. All sections will be shown in this report.
- 2. Click the Back button to go back to the previous page.
- 3. Click the Preview PDF button to view the report in Portable Document Format (PDF) format. (Refer to **4.5.1 Preview PDF Field Corrective** Action (FCA) Report)

4.5 PREVIEW PDF

4.5.1 Preview PDF Field Corrective Action (FCA) Report

- a. There are two (2) types of Preview PDF:
 - 1. A part of Preview PDF for Draft Report will be shown below.



I. The Declaration Section will not be included in the Preview PDF for Draft Report.

6. Email address

Medical Device UTHORIT MALAYSIA Field Corrective Action Report Notification Section A : Field Corrective Action Report 1. MDA FCA Reference Number MDA/FCA/PX0345-79741604-2022 1.1 MDA MPR Reference Number MDA/MPR/P0235-48710369-2022 2. Type of Report Notification 3. Title of Field Corrective Action (FCA) etret 4. Type of Field Return Section B : Establishment Particulars 1. Name of Company Medical Device Authority Development Team (ICT) 2. Company Address 011, JALAN CYBERIA 1, CYBERJAYA 3. Contact Person Name HOST 011 4. Job Title MANAGER 5. Telephone Number 0123456789

host011@sebumbung.com

2. A part of Preview PDF for Submitted Report will be shown below.

4.6 EDIT REPORTING

4.6.1 Edit Notification Report

a. A part of the edit Notification Report page will be shown below.

4. Evaluation of the risk associated with affected medical davice (Health Hazard Evaluation Report)	Choose Files No file chosen Ke uplied the roll state all preven time. Multiple the splind are allowed by the maximum size of the true time splinded sourt are exceed 225/26
5. Background information and reason for the FCA?*	Lorem (psum
6. Root Cause*	Lorum (psum ** The root cause is based on what is initial cause the masces to initiated the PCA. Usually, the root cause is initiated that before any convertive action is black
7. FCA plan and action to be taken (corrective action)*	
8. Advice on actions to be taken by the distributor and the user*	

- 1. Users can update all information in this report.
- The process to submit the updated report will be the same as submitting a new report. (Refer to 4.3.1 Create New Notification Report)

4.6.2 Edit Follow Up Report

a. A part of the edit Follow Up Report page will be shown below.

 Section F : Follow Up 	
1. Follow Up (Progress of FCA, together with reconciliation status and/or effectiveness	Lorem (psun)
check and its method;* 2. Has the FCA able to completed within the proposed timeline?*	Yes No dd/mm/yyyy

- 1. Users can update all information for this section in this report.
- The process to submit the updated report will be the same as submitting a new report. (Refer to 4.3.2 Create New Follow Up Report)

4.6.3 Edit Return from MDA Report

a. A part of the edit Return from MDA Report page will be shown below.

Section D : FCA Proposed Plan and Action (Co	rrective Action)	
· FOA Director Foat in the second	loren-josum	Satisfied: No
1. FCA Planned by Establishment*	** This is summary information of the FCA planned by the establishment 2f you have documents related to this action planned, planne splanned it in Section II of this from.	Comment:
Section E : FCA Information		
1. Did the FCA arise due to an incident?*	No	Yes
1.1 If yes, what is the category of incident?		Yes
2. Did this incident occur in Malaysia*	No 1	Yes
3: If yes, has the incident been reported to MDA?*	No	Yes
4: Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report)	Remark section	Yes
5: Background information and reason for the FCA*	korem ipsum	Yes
6: Root Cause*	loram ipsum	Setisfied: No Comment:
	¹¹ The cost cause is based on what is initial cause the sensor to initiated the FCA. Usually, the cost cause is identified from below any consentity action is taken.	- Wetterheitte
Declaration		
I hereby attest that the information and attachme	nt provided on this reporting is / are correct, completed and current to th	is data.*
 I understand and acknowledge that is an offence misloading.* 	under Section 76 of Act 737, to make sign or furnish any declaration, or of	her document which is untrue, inaccurate or
Person Responsible HOST OII for the Establishment		
Job Title MANAGER		
Telephone 0123456789		
Email Address host0100ebumbung	com	
	Button Section	2 Back Preview PDF Submit

- 1. Users can only update the information that has a 'No' remark in this report.
- 2. Button section.
 - I. This section displays all buttons in the Notification Report.



II. Click button to go back to the previous page. The pop-up will be display as below:

	Back Confirmation Pop-up
	Back Confirmation Click "Yes" button
	Are you sure to go back to the previous page? 2
	Click "No" 3 No Yes
	Back Confirmation Pop-up.
	 Click the revious page.
	\circ Click the button to stay on the same page.
111.	Click the button to view the report in Portable Document Format (PDF) format. (Refer to 4.5.1 Preview PDF Field Corrective Action (FCA) Report)
IV.	Click the Submit button to submit the updated report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.7 DELETE REPORTING

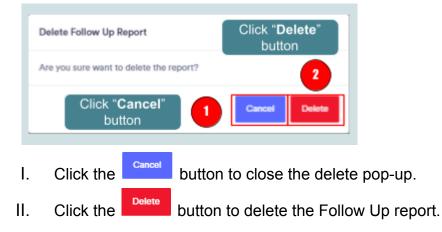
4.7.1 Delete Notification Report

a. Click the **Delete** button to delete the Notification report and the pop-up will be displayed as below:

	Delete Notification Report	Click " Delete " button	
	Are you sure want to delete the form?	2	
	Click "Cancel" button	Cancel Delete	
I.	Click the Cancel button	to close the delete	e pop-up.
II.	Click the Delete button	to delete the Notifi	cation report.

4.7.2 Delete Follow Up Report

a. Click the **Delete Follow Up** button to delete the Follow Up report and the pop-up will be displayed as below:



4.8 FCA REPORT OVERDUE

	FCA Dashboard > FCA Overdae Report	15					
List o	f FCA Overdue Reports						
				Tab	le Filtering	0	Search Q
No.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/P0232-93729407- 2021	MEDICAL TESTORD	28/12/2021	67/01/2022	Follow Up	Overdue	00View Hill.og Bit Extend Date (5/2)
2	MDA/FCA/P0349-90198368- 2022	MEDICAL TESTONA	0.63/2022	24/03/2022	Closure	Overdue	@View i∃Log ∰ Extend Date (0/2)
8	MDA/FCA/PX0367-64210186- 2022	MEDICAL TESTONA	25/02/2022	Action Button (Overdue) Follow Up	2 Overdue	00View I≡Log ≜ Extend Date (5/2)
4	MDA/FCA/P0371-83372451-2022	MEDICAL TESTONA	14/03/2022	08/04/2022	Follow Up	Almost Overdue	(記View) 語Log 第Follow Up 簡 Extend Date (5/2)

- a. List of FCA Overdue Report will be displayed as above:
 - 1. Table Filtering shown as below:

		Enter a	ny related	keyword
Information	6	Search	2	۹ 🛛
Tooltip				Click " Search " icon

I. User can click the ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information	×
Searching Steps	
 Type any keyword:- FCA Reference Number FCA Report Type Medical Device Name Date Submission (yyyy-mm-dd) (Eg: 2020-01-01) Date Proposed Completion (yyyy-mm-dd) (Eg: 2020-01-01) Status Click the search icon button (Q_ to find the report. 	
Close	,

- Click the × button or button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click the \bigcirc icon and the system will display the result.
- 2. Action Button for Overdue Status:
 - I. Click the View button to view the report. (Refer to 4.4.1 View Field Corrective Action (FCA) Report)
 - II. Click the button to view the reporting log and the pop-up will be displayed as below:

No.	Date	Stage	Status	Officer
2	28/04/2022 \$7:09:07	Overdue	Field Corrective Action (FCA) Follow Up report has Overdue	System
1	28/04/2022 \$7:07:42	Almost Overdue	Field Corrective Action (FCA) report are almost Overdue	System
				Close

IV. Click the Extend Date (0/2) button to request extension time and the pop-up will be displayed as below:

Do you need more extention time? (0/2) **REMINDER: Establishment can request to extend the date up two (2) times one (1) application. Request for extension 30 days time:* 90 days 120 days Justification*	× only for
one (f) application. Request for extension 30 days time:* 90 days 120 days	only for
time:" 90 days 120 days	
90 days	
-	
Justification*	
	le
Clear Con	firm

information.

Click the confirm button to submit the request for extension time.

- 3. Action Button for Almost Overdue Status:
 - I. Click the View button to view the report. (Refer to 4.4.1 View Field Corrective Action (FCA) Report)
 - II. Click the button to view the reporting log and the pop-up will be displayed as below:

-	Dete		Bala	Officer
5	10-02-9322 08-52-59	Almost: Overthee	Field Connective Action (FCA) report are almost Overdue	System.
*	26.453.0522 10.32.49	Evolution	Fullew Up report has been listen in Establishment By Nord Dynas Kird, Mold Nor	Nural Diyana bisti Mohd Nor
	26-02-9022 08:38:54	Dealt	Field Corrective Action (FCR) Follow Up report has been caved as draft.	HOET ON
2	26-52-5522 08-36-28	Scheelford	Parket Connection Retriev (PCR) Notification report has lower-Submitted	HOET ON
,	25-03-9322 1553-84	Death	MEA/MPR/P0275-7595895-2022 opened a new Field Convertine Action (FCA) application. The evention data is 39/92/2022	HOET ON

➤ Click the

button to close the pop-up.

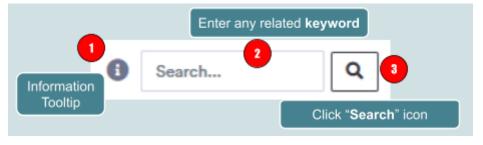
- III. If the report status is Almost Overdue, user have two (2) actions to choose which are:
 - Click the Follow Up button to continue the report and submit the report before Overdue. (Refer to 4.3.2 Create New Follow Up Report)
 - Click the Extend Date (0/2) button to request extension time and the pop-up will be displayed as below:

Do you need more exte	ention time? (0/2) X
**REMINDER: Establishment one (1) application.	can request to extend the date up two (2) times only for
Request for extension	🔿 30 days
time:*) 90 days
	🔿 120 days
Justification*	
	A
	Clear Confirm
	Clear
0	Click the button to clear all the
	information.
0	Click the confirm button to submit the
	request for extension time.

4.9 FCA REPORT COMPLETED

Field (Corrective Action										
Dashboard	Durbboard > FCA Durbboard > FCA Completed Report										
List o	of FCA Completed Report										
				Tab	le Filtering		O Search Q				
No.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action				
1	MDA/FCA/P0229-96246492-2021	MEDICAL TESTORIC	94/02/2022	15/05/2022	Closure	Completed	Visw III Log Acknowledgement Latter				
Showin	ng t of t entries.			_ ^	ction Button						

- a. List of FCA Completed Report will be displayed as above:
 - 1. Table Filtering shown as below:



II. User can click the ⁽¹⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information			×			
Searching St	eps					
1. Type an						
	CA Reference Number CA Report Type					
	ledical Device Name					
	ate Submission (уууу-mr					
	ate Proposed Completio tatus	n (yyyy-mm-dd) (Eg: 20)	20-01-01)			
2. Click th	e search icon button (Q) to find the report.				
			_			
			Close			
			_			
	lick the $ imes$	button or	Close	buttop	to alago	tha
	lick the	bullon of		Dullon	to close	tne
р	op-up.					
Enter ar	y related ke	evword (bas	sed on i	informati	on aiven).
	,	- , (- J	,
SI: 1 /1	Q .					

- V. Click the \square icon and the system will display the result.
- 2. Action Button:

- XI. Click the View button to view the report. (Refer to 4.4.1 View Field Corrective Action (FCA) Report)
- XII. Click the button to view the reporting log and the pop-up will be displayed as below:

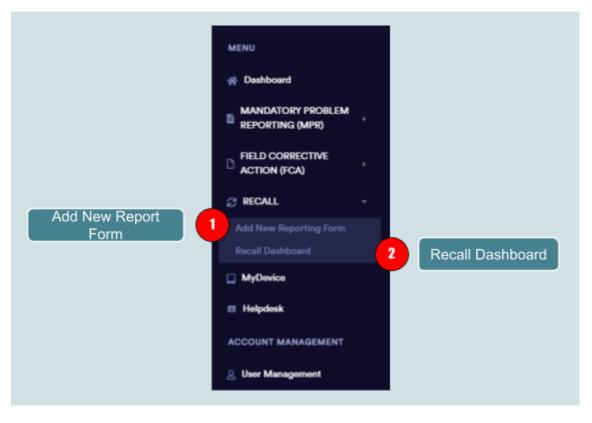
No.	Date	Stage	Status	Officer
١	54/02/2022 01:27:36	Submitted	Field Corrective Action (FCA) Closure report has been Submitted	HOST 011
2	94/02/2022 01:21:30	Extend Date	The report to extend new completion date has been approved.	Nurul Diyana binti Mohd Nor
3	94/02/2022 01:20:22	Extered Date	Field Corrective Action (FCA) application has been request for Extend Date	HOST 011
4	28/01/2022 95:56:44	Overdue	Field Corrective Action (FCA) Additional Follow Up report has Overdue	System
				Close

XIII. Click the Acknowledgement Letter button to view the acknowledgement letter that the system will generate for the user. The acknowledgement letter will be displayed as below:

/ 1	en antigen of the sector for addit Walaysia 11 Time Anerope II, minute 1975.		Na Language and State
		Our Reference Number Deta	: MDA/FCA/P029-96346482-3021 : 04/04/2022
HORT DR Medical Device Authority Develo DT, JALAN CYBERA 1, CYBERA Dr Marten,			
Advantagement Receipt of Fig			g Field Safety Notification communication from
MDA FCA Bel, Number	AND A DOL NOT	1000-082484-0021	
Report Type	: Destruction	C The second root	
Title	t berang 10H		
Design Name	MEDICAL TEST	140	
MDA Registration Number			
Initial Date	:04/04/3022		
Chasers Date	15/05/2022		
CA8 Name	: GAB 0110		
2. Please be advised to monitor of Thank you. Director Registration, Licensing and Enfor Medical Device Authority Medical Device Authority Ministry of Health Maleysia	cement Division		e actions manfioned eleves.
This is a computer generated do	ument. No signatur	o is required.	



5.1 RECALL SIDEBAR



- a. Recall Sidebar will be displayed as above:
 - 1. Create New Notification Report
 - I. Create New Notification Report will display the create page for Notification report.
 - 2. Recall Dashboard
 - I. Recall Dashboard will display Recall main dashboard.

5.2 RECALL DASHBOARD

rd		Recall Report	Counter				
	Notification Report		Fallow U	Final Report			
Total of Rep	orting Return from	MDA	Total of Reporting	Return from MDA	Total of Reporti	ng Ri	atum from MDA
12	0		2	0	3		1
1 Nore Property	Reporting Table	Click "Add Ne	W Reporting" b		6 Closure R	porting Table (0]
•	Reporting Table	5 Clic Rep	Overdue Reporting To k "Overdue porting Table"	Ne(5)	Click "Closu Reporting 1	ire 'able" tab	
4 Click *I	Reporting Table	5 Clic	Overdue Reporting Ta	Ne(5)	Click "Closu Reporting T	ire 'able" tab	
Click *I Table*	Reporting Table Reporting tabs	5 Clic Rep Medical Device	Overdue Reporting Ta k "Overdue porting Table" Date of Reporting	tabs	Click "Closu Reporting T	ire 'able" tab)s q

- a. The Recall Dashboard page will be displayed as above:
 - 1. Recall Report Counter (Refer to 5.2.1 Recall Report Counter).
 - 2. Click the Add New Reporting Form button to open a new report Notification (Refer to <u>5.3.1 Notification Report</u>).
 - 3. "Reporting Table" tabs (Refer to <u>5.2.3 Reporting Table</u>).
 - 4. "Overdue Reporting Table" tabs (Refer to <u>5.8 OVERDUE</u> <u>REPORTING</u>).
 - 5. "Closure Reporting Table" tabs (Refer to <u>5.9 CLOSURE</u> <u>REPORTING</u>).

5.2.1 Recall Report Counter



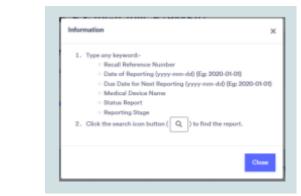
- a. There are three types of reports counter will be displayed as above:
 - 1. Notification Report Counter Statistic for Notification Report.
 - 2. Follow-Up Report Counter Statistic for Follow -Up Report.
 - 3. **Final Report** Counter Statistics for Final Report.
 - 4. Total reporting form.
- b. Users are allowed to click on the counter number to see a list of reports running at each report stage:
 - 1. **List of Total Reporting -** Displays a list of all reports at the reporting stages (Notification, Follow-Up,Final) with Draft and Submitted status.
 - I. A part of the total reporting list will be shown below.

	I > Final Total of Reporting Table						
* R	al Total of Reporting					1	Table Filtering
						0	Search
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date for Next Reporting (dd/mm/yy)	Reporting Stage	Status	Action
1	MDA/Recall /P02th-66238329-2022	MEDICAL TESTORIC			Final	Draft	i≡Log Ø View Ø folk
2	MDA/flecall /P0177-71029181-2022	MEDICAL TESTONO	13/02/2022	-	Final	Submitted	l≣Log @ View ■ Acknowledgement Letter
3	MDA/Recall /P0190-92960132-2022	MEDICAL TESTORB	16/02/2022		Final	Submitted	(El Log (B) View

- ➤ Table Filtering
 - Users can fill in the 'Search...' field to find the reporting that the user wants to search. User need to

click click button to find the reporting.

- User can click ¹ button to get more information about filter tables.
- The information pop-up below will be displayed :



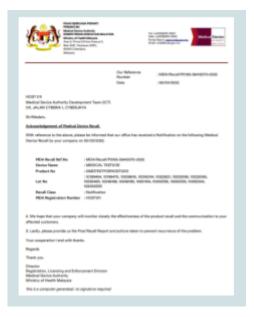
➤ Action buttons

0

Click button to view report Log Details.
 Log details will be display as below:

0		eference number ation Log Datails : MDA	/Recall/P	Report log details	
	No.	Duto 01/04/2022 10.35.34	Stege Draft	Status Officer Becall NotiFication report has been saved as druft. HOST Off	
				Click "close" button	
	•	Report R Report lo		rence Number. etails.	
Click pop-up	> 5.	button	or	close button to close th	e

- Click View button to view the report (Refer to <u>5.4</u> <u>VIEW RECALL REPORT</u>).
- Click Celetic button to update all information in the report (Refer to <u>5.6 EDIT REPORT</u>).
- Click ^{EFollow-Up Report} button to open Follow Up Report (Refer to <u>5.3.2 Follow-Up Report</u>).
- Click Final Report button to open Final Report (Refer to <u>5.3.3. Final Report</u>).
- Click Acknowledgement Letter button to view and print acknowledgement letters.
 - Acknowledgement letters will be display as below:



- 2. List of Return from MDA Displays a list of all reports at the reporting stages (Notification, Follow-Up,Final) with Return from MDA status.
 - I. A part of the return from MDA LIST will be shown below.

Main Deribboa	1.3 Final Rature from MOA Tabla						
× 6	al Return from MDA						
						Table Fi	itering
					_	G Search	Q
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (dd/mm/yy)	Reporting Stage	Status	Action
	MDA/Recall /P0196-91736365-2022	MEDICAL TESTONB	25/02/2022	10/04/2022	Final	Return from MDA	l⊟Log 90 View []‴Edk

➤ Table Filtering

• Users can fill in the 'Search...' field to find the reporting

that the user wants to search. User need to click $\[\] \]$ button to find the reporting.

- User can click ^① button to get more information about filter tables.
- The information pop-up below will be displayed :

 Type any keyword:- 	
 Recall Reference Numb 	
 Date of Reporting (yyyy 	r-mm-dd) (Eg: 2020-01-01)
Due Date for Next Report	orting (yyyy-mm-dd) (Eg: 2020-01-01)
 Medical Device Name 	
 Status Report 	
 Reporting Stage 	
2. Click the search icon button (Q) to find the report.
	Q_) to find the report.

Action buttons

Click button to view report Log Details.
 Log details will be display as below:

No.	Date	Stage Status Officer	
1	05/04/2022 10:35:34	Draft Becall Notification report has been saved as draft. HOST Of	
		Click "close" button	Icose
		eport Reference Number. eport log details.	
	• C	ick × button or close butt	on to clo

• Click Click button to update all information in the report (Refer to 3.7.3 Edit Return From MDA).

5.2.2 Open New report (Notification)

0

a. The Recall new report page will be as shown (Refer to <u>5.3.1</u> <u>Notification Report</u>):

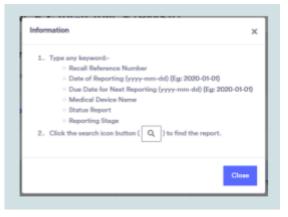
5.2.3 Reporting Table

a. The Reporting Table tabs will be shown as below:

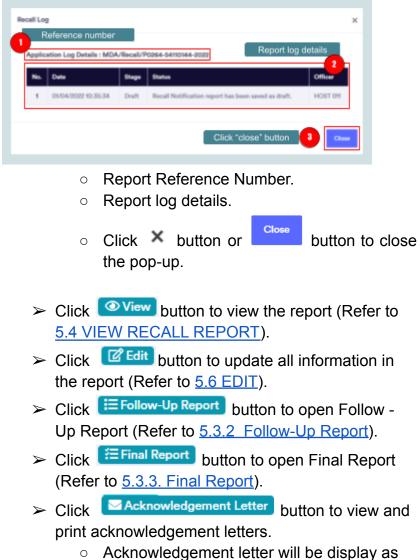
	Reporting Table		Overdue Reporting			Closura Reporting	
Repo	rting Table Tabs					2 Table	Filtering
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date for Next Reporting (dd/mmv/yy)	Reporting Stage	Action b	uttons Action
5	MDA/Recall /P0225-63024980-2022	MEDICAL TESTONA	31/03/3023		NotiFication	Druft	(H Log (H View) (C Gen (C Gen (C Selector)
2.	MDA/Recall /#9207-88277670-2022	MEDICAL TESTONG	30/03/2012	08/04/2022	Fallow Up	Submitted	CE Log CE Vice Giffing Report
l	MDA/Recall /P0896-36412070-2022	MEDICAL TESTONO	30437-9018	07/04/2022	NotPlatian	fadewitted	18 Log 19 Vice 18 Follow Up Report
4.	MDA/Recall /F92104-45539926-2022	MEDICAL TESTONA	25/02/2022	28-02-2022	Follow Up	Batum from MCA	CE Log CE Vices CE Este
6	MDA/Recall /POPIs-652381299-9522	MEDICAL TESTONO			First	Druft	(Eling) (Eling) (Eling)

- 1. **Reporting Table Tabs** Display a list of all reporting stages (Notification, Follow-Up,Final) with Draft,Submitted, and Return from MDA status.
 - I. Table Filtering
 - Users can fill in the 'Search...' field to find the reporting that the user wants to search. User need

- User can click ¹ button to get more information about filter tables.
- > The information pop-up below will be displayed :



- II. Action Button
 - Click Elog button to view report Log Details.
 - Log details will be display as below:



below:

Char Balances INCA Result PORS 34 (9017) 2021 Review - 86/54/5021 POIT OF Medical Device Address (Device Address Taxon 30(1)) Review - 86/54/5021 POIT OF Medical Device Address (Device Address Taxon 30(1)) Review - 86/54/5021 Point Maximum Biology Device Address (Device Address Taxon 30(1)) Review Medical Device Address (Device Address (Device Address Taxon 30(1)) Maximum Life Maximum Life Maximum Address (Device Address Taxon 30(1)) Device Medical Device Address (Device Address (Device Address 30(1)) Mite Maximum Life Maximum Address Address (Device Address 30(1)) Device Medical Device Address 30(1) Mite Maximum Life Maximum - 10(1) Device Maximum - 10(1) Maximum Life Maximum - 10(1) A Leafly, privation Maximum - 10(1) Maximum Life Maximum - 10(1) Maximum - 10(1) <th>A TAKE MANAGEMENT</th> <th>Autority attention and attention of the second to the second to</th> <th></th> <th>No. 1 and and a state of the st</th> <th>Device to anti-</th>	A TAKE MANAGEMENT	Autority attention and attention of the second to the second to		No. 1 and and a state of the st	Device to anti-
Markan Umban Anthonip Orangament Yama (ICT) Bir, ALANC WEAK, SCHERAMUNK Bir, Mank Weither, SCHERAMUNK Advanced Scheramunk, SCHERAMUNK Markan Scheramunk		North	é.er		9-2022
Alcanation Alcanation We describe the shore, please is identical that ar office has excelled a Notification on the balancing Medical Desire Mice a flag new exception on Notification Mice a flag new exception on Notification Mice a flag new exception on Notification Mice a flag new exception	Medical Device Authority Develop				
With reference to the above, plasma to informate all our official has wanded a Natification on the Velocity Medical Desire Hamilton and Hamilto	ScrMadam,				
With reference to the above, plasma to informate all our official has wanded a Natification on the Velocity Medical Desire Hamilton and Hamilto	Admoniatigement of Visitual De	tion Recall.			
Indication INDICATION Product His INDICATION Indication INDICATION Indication INDICATION Indication INDICATION Indication INDICATION Name Indinininininininininininininini			for har work	ved a Natification on the following h	helical
Product His : GARCTESTINDED Let His : GARCTESTINDENCITYPED Let His NUMBERS, UNINESS, UNINES			10070-0088		
i consense, services, sciences,					
Let Ne VEEDBARD, CORRENT, REPERD, REPE	Product No.				
HEA Registration Number : HEATERS	Lot No	1220-01, 1240-08, 129			
We hope that your company will monitor closely the effectiveness of the product naced and the communication to your affected meanment. So Lardy, place and the final Recall Report and actions taken to prevent recurrence of the problem. Tour comparation I and addit deales. Reports That you. That you. That you. That you.	Recall Class	Notification			
a Meriade reactances. 3. Lanty, glassa provide at the Final Recall Report and actions taken to prevent recommon of the problem. You comparation I and with thanks. Regards Theat you. Similar Registration, Liberaturg and Educament Division. Medicated Device Analysis.	HEA Registration Number	HOSTIN			
Region for The edity ress Elementaria Region (and constraints) and Elementaria Division Region (and and and and and and and and and and	affected contempts.				ation to your
There yes: Descent Registration, Clanning and Enforcement Division Medical Device Anthony	Your cooperation I and with thank				
Disense Registration, Licensing and Enforcement Division Medical Division Authority	Reports				
Registration, Connaing and Enforcement Division Medical Device Authority	Thank you.				
	Registration, Licensing and Enfort Medical Device Authority	enert Division			
this is a computer pervented, no algorithms required	this is a computer generated, no	grature required			

5.2.4 Overdue Reporting Table

a. The Overdue Reporting Table will be as shown (Refer to <u>5.8</u> <u>OVERDUE REPORTING</u>):

5.2.5 Closure Reporting Table

a. The Closure Reporting Table will be as shown (Refer to <u>5.9</u> <u>CLOSURE REPORTING</u>):

5.3 CREATE RECALL REPORT

5.3.1 Notification Report

a. Click the Add New Reporting Form button to create Notification report and the Notification page will be displayed as below:

	Medica	I Device Recall Form
(*) - required		
	VE AN AUTO SAVE FUNCTION Diseased in the	e "BACK" button at the bottom of the page and click "YES" to save the form as a draft.
The page boas not not	TE ACTING TO THE E POINT EDUCE. PICKET CALL IN	E DAVER. VERME IT WE WINTER IT WE page and CAUR. I KIP TO SAFE WE DITH AN A WHAT.
Recall Reference No.	MDA/Recall/P0219-97047593-2022	Recall Reference Number
 Section A : Medical 	Device Recall Report Form	Section A: Medical Device Recall Report Form
 Section B : Establish 	Iment Details	Section B: Establishment Details
 Section C : Affected 	d Medical Device Details	Section C: Affected Medical Device Details
 Section D : Notifica 	tion Report Section : Recall Information 5	Section D: Notification Report Section: Recall Information
✓ Section D : Notifica	tion Report Section : Recall Information	Section D: Notification Report Section: Recall Information
✓ Section D : Notifica	tion Report Section : Recall Information	Section D: Notification Report Section: Recall Information
		Section D: Notification Report Section: Recall Information
sclaration 6	Declaration	
eclaration 6	Declaration	his reporting is / are correct, completed and current to this date .*
eclaration 6	Declaration e information and attachment provided on the owledge that is an offence under Section 76	
I hereby attest that the understand and ackn which is untrue, inacci	Declaration Information and attachment provided on the owfedge that is an offence under Section 76 urate or misleading.*	his reporting is / are correct, completed and current to this date .*
eclaration 6 I hereby attest that the I understand and ackn which is untrue, inacco rson Responsible	Declaration e information and attachment provided on the owledge that is an offence under Section 76	his reporting is / are correct, completed and current to this date .*
I hereby attest that the I understand and ackin which is untrue, inacci rson Responsible the Establishment	Declaration e information and attachment provided on the owfedge that is an offence under Section 76 urate or misleading.* HOST Off	his reporting is / are correct, completed and current to this date .*
I hereby attest that the I understand and ackin which is untrue, inacci rson Responsible the Establishment	Declaration Information and attachment provided on the owfedge that is an offence under Section 76 urate or misleading.*	his reporting is / are correct, completed and current to this date .*
I hereby attest that the I hereby attest that the I understand and ackn which is untrue, inacci rison Responsible r the Establishment b Title	Declaration e information and attachment provided on the owfedge that is an offence under Section 76 urate or misleading.* HOST Off	his reporting is / are correct, completed and current to this date .*
eclaration 6	Declaration e information and attachment provided on the owledge that is an offence under Section 76 urate or misleading.* HOST 011 MANAGER	his reporting is / are correct, completed and current to this date .*
eclaration 6 I hereby attest that the I understand and ackn	Declaration I information and attachment provided on th owfedge that is an offence under Section 76 urate or misleading.• HOST 011 MANAGER 0123456789	his reporting is / are correct, completed and current to this date .*

1. Recall Reference Number.

Recall Reference No.	MDA/Recall/P0217-80467372-2022

- I. Recall Reference Number is auto-generated by the system.
- 2. Click the Section A: Medical Device Recall Report Form.
 - I. Section A will be display as below:

 Section A : Medical Device 	e Recall Report Form
1. Recall Initiated by *	 Establishment (Voluntary Recall) Authority (Mandatory Recall)
2. Type Of Report	 Notification / Preliminary Report Follow Up Report Final Report

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Question 2 is autofill by system based on report type.
- 3. Click the Section B : Establishment Details
 - I. Section B will be display as below:

MDA Establishment License No.*	KP-HOST011		
2. Name of Establishment *	Medical Device Authority Development Team ()	CT)	
5. Establishment Address *	01, JALAN CYBERIA 1, CYBERJAYA63000, SEL	ANGOR	
L Contact Person Name *	HOST DH		
s. Job Title •	MANAGER		
5. Tel No. •	0123456789	7. Fax No. •	0123456789
8. Email Address •	host011@ssbumbung.com		
2. CAB Name *	CARE CERTIFICATION INTERNATIONAL(M) SE	CH8.M	_

- II. All information in this section will be auto-filled by the system
- 4. Click the Section C : Affected Medical Device Details.
 - I. Section C will be display as below:

 Section C : Affected Medical Device De 	aik		
1. MDA Device Registration No. •	Select NDA Registration Number		
2. Affected Device Name *			
3. Device intended use *			
4. Class of Device*			
5. Device Hisk *			
	Table of Device Details*		
	Table of Device Details* (Establishment may download file template exact file & up 3. Template 1 : Template for Table of Afficient D		
	(Establishment may download the template excel file & up	erine Details xis 🛓	
	(Establishment may download the template excel file & up 1. Template 1 : Template for Table of Affected De	erine Details xis 🛓	
Product No. / Catalogue N	(Establishment may download the template encod file & up 3. Template B : Template for Table of Afficient De 3. Example B : Example for Table of Afficient De	erine Details xis 🛓	Quantity
Product No. / Catalogue N	(Establishment may download the template encod file & up 3. Template B : Template for Table of Afficient De 3. Example B : Example for Table of Afficient De	rrise Details.xts 🛓 rrise Details.xts 🌲 Serial Namber / UDI Code (d'applicable)	Quantity
Product No. / Catalogue N	(Establishment may download the template encod file & up 3. Template 1 / Template far Table of Affected Dy 3. Example 1 / Example far Table of Affected Dy a. / Identifier No. Lot / Batch No.	rrise Details ats & rrise Details ats & Serial Number / UDI Code Of applicable) splay	Guandity rtal 0
Product No. / Catalogue 1	(Establishment may download the template encod file & up 3. Template 1 / Template far Table of Affected Dy 3. Example 1 / Example far Table of Affected Dy a. / Identifier No. Lot / Batch No.	rrise Details ats & rrise Details ats & Serial Number / UDI Code Of applicable) splay	nal O
	(Establishment may download the template encod file & up 3. Template 1 / Template far Table of Affected Dy 3. Example 1 / Example far Table of Affected Dy a. / Identifier No. Lot / Batch No.	rrise Details ste & rrise Details ste & Serial Number / UDI Code (if applicable) isplay	nal O
Product No. / Catalogue J Product No. / Catalogue J 7. Accessories/ Associated Devices Affected *View	(Establishment may download the template encod file & up 3. Template 1 / Template far Table of Affected Dy 3. Example 1 / Example far Table of Affected Dy a. / Identifier No. Lot / Batch No.	rrise Details ste & rrise Details ste & Serial Number / UDI Code (if applicable) isplay	nal O
7. Accessories/ Associated Devices Affected	(Establishment may download the template encod file & up 1. Template 11 : Template far Table of Affected Dy 2. Example 11 : Example far Table of Affected Dy a. / Identifier No. Lot / Batch No.	rrise Details ste & rrise Details ste & Serial Number / UDI Code (if applicable) isplay	nal O

- II. Click the dropdown button on MDA Device Registration No.(Question 1) to choose a registered device number.
- III. All information in this section will be auto-filled by the system based on the chosen MDA Device Registration number except Table of Device Details and question 7.
- IV. Table of Device Details:

	Ta	ble of Device Details*		
		the template excel file & uploa		
		late for Table of Affected Devic gle for Table of Affected Devic		
Template for Ta	able of Affected			
			Serial Number / UDI Code	
Device	Details	Lot / Batch No.	(if applicable)	Quantity
Device	0.	Lot / Batch No.	(if applicable)	Quantity

- > Table of Device Details will be displayed as above.
- There are two (2) template for Table of Affected Device Details that user can download which are:
 - Example for Table of Device Details
 - Template for Table of Device Details
- Users are required to use the template provided to upload it in the table.
- The Add Details of Affected Devices button will be enabled after the user chooses any MDA Device Registration number as shown below:
- By clicking Add Details of Affected Devices button, the system will display Details of Affected Devices page shown as below:

		Table of Device Details • • •<	
1. Up	sed file:	Browses No The selected. *Ke-spical file-will deline all process infernation.	Import File
dante	ended file of affected 2 Ided File Section	 Template for Table of Affected Device Dataits (MDA, Recall, J 	P0263, 79747738, 2002) (+G-94011) als
No	Product No. / Catalogue No. / Identifier No.	Lot / Batch No.	Serial Number / UDI Code (If applicable) Gu 3 Action
L.	AIMB-28-70	10222636, 10238909, 10245880, 10250361, 10250362, 10250363, 10262346, 10269346, 10269483	Action Button
			Total 100
		Click "Next" button	A Ned

> In the Upload File Section, users can choose the file that

needs to be uploaded by clicking Choose File button and

Import File

button will be enabled after the user chooses the

file. Then click button to import the file in the table.

- In the Uploaded File Section, it will display the file that the user uploads.
- > In the Action column, it has two (2) button that user can use:
 - User can click **C** Edit button to update the affected devices details in the table and the system will display the popup to update the details of affected devices shown as below:

	Edit details of affe	cted devices
	Product No. / Catalogue No. / Identifier No.	AIMB-28-70
	Lot / Batch No.	10222636, 10238909, 10245880, 10250361, 102503
	Serial Number / UDI Code (if applicable):	Click " Update " button
	Quantity: Click	x "Clear" button
CI	ick " Close " b	outton Clear Update
-	Click the	Close button to close the popup.
-	Click the information	clear button to clear all the on.
•	Click the information	Update button to update the on.
 User can of from the tag 		button to delete the information
Click the page section	Next C.	button to back to the previous

V. The updated Table of Device Details will be displayed in Section C as shown below:

		Establishment may download the template exort file & splited at given file section) 1. Template 🖥 : Template for Table of Affrected Device Details.sis 🏯 2. Example 🖥 : Example for Table of Affrected Device Details.sis 🏯		
No.	Product No. / Catalogue No. / Identifier No.	S Lot / Batch No.	erial Number / UDI Code (if applicable)	Quantity
з.	AIMB-28-70	10222636, 10238909, 10246880, 10260361, 10260362, 10250363, 10262545, 10262546, 10269483	nh	100
			Total	100

VI. Click Edit / Add Details of Affected Devices details of affected devices.

button if users want to edit add

- 5. Click the Section D : Notification Report Section: Recall Information.
 - I. Section D will be display as below:

 Section D : Notification Report Se 	rtion : Recall Information	
1. Date of report	11-03/3022	
2. Date of commencement of Recall by manufacturer *	dal / mm./ yypy	
(Vote: Please click the toollige)		
3. Did the Recall arise due to an adverse incident? •	0 Yes	
	O No	
4. Did this advarse incident occur in Malaysia? *	 Yes No 	
5. Has the adverse event been	<u>े १८४</u>	
reported to MEA? * *(Plase edent oily car)	O No	
6. Evaluation of the risk	Draws. No fits associat.	
associated with affected device (Net: Health Reard System Report)	Browner, Two Tests on another, Browner, Theorem Tests, and Browner, Theorem Tests, and Browner, Tests, and and and not record 20.48	<u> </u>
7. Reason for Recall *	Act: Pataert Davice Interaction Problem Act: Manufacturine, Devicement Contention Problem	
2. Reason for Recall •	AOI: Patient Device Interaction Problem AOI: Manufacturing, Packaging or Shipping Problem AOI: Channical Problem	
z. Rasson for Recall *	Act: Manufacturing, Packaging or Shipping Problem	
z. Raason for Racall *	AOI: Manufacturing, Packaging or Shipping Problem AOI: Chamical Problem	
z. Raason for Racall *	AOI: Manufacturing, Packaging or Shipping Problem AOI: Chamical Problem AOI: Matural Integrity Problem	
z. Raason for Racall *	AOE: Monufacturing, Packaging or Shipping Problem AOE: Chamical Problem AOE: Material Integrity Problem AOE: Machanical Problem	
2. Raason for Racall *	AOE: Monufacturing, Packaging or Shipping Problem AOE: Chamical Problem AOE: Matural Integrity Problem AOE: Machanical Problem AOE: Optical Problem	
2. Raason for Racall *	A02: Manufacturing, Packaging or Shipping Problem A03: Chamical Problem A04: Material Integrity Problem A06: Machanical Problem A06: Optical Problem A06: Optical Problem A07: Electrical /Electronic Property Problem	
2. Raason for Racall *	AOE: Manufacturing, Packaging or Shipping Problem AOE: Chamical Problem AOE: Material Integrity Problem AOE: Optical Problem AOE: Electrical /Electronic Property Problem AOE: Calibration Problem	
2. Rasson for Racall *	A02: Monufacturing, Packaging or Shipping Problem A04: Chemical Problem A04: Material Integrity Problem A06: Optical Problem A06: Optical Problem A06: Calibration Problem A06: Calibration Problem A06: Coptut Problem	
2. Rasson for Recall *	A02: Manufacturing, Packaging or Shipping Problem A03: Chemical Problem A04: Material Integrity Problem A06: Optical Problem A06: Optical Problem A06: Calibration Problem	
2. Basson for Recall *	A02: Manufacturing, Packaging or Shipping Problem A03: Chamical Problem A04: Material Integrity Problem A06: Machanical Problem A06: Optical Problem A06: Optical Problem A06: Calibration Problem A08: Carparature Problem A08: Tamparature Problem A09: Tamparature Problem	
2. Basson for Recall *	A02: Manufacturing, Packaging or Shipping Problem A03: Chemical Problem A04: Material Integrity Problem A06: Mochanical Problem A06: Optical Problem A06: Optical Problem A07: Electrical /Electricatic Property Problem A08: Calibration Problem A08: Output Problem A09: Output Problem A02: Temperature Problem A03: Calibration Problem A04: Temperature Problem A04: Temperature Problem A04: Temperature Problem	
2. Rasson for Recall •	A02: Manufacturing, Packaging or Shipping Problem A03: Chemical Problem A04: Material Integrity Problem A04: Material Integrity Problem A05: Optical Problem A05: Optical Problem A05: Calibration Problem A06: Calibration Problem A06: Calibration Problem A06: Temperature Problem A07: Temperature Problem	
2. Rasson for Recall •	AD2: Manufacturing, Packaging or Shipping Problem AD3: Chemical Problem AD4: Material Problem AD4: Material Integrity Problem AD5: Optical Problem AD5: Optical Problem AD5: Calibration Problem AD5: Output Problem AD5: Temperature Problem	
2. Rasson for Recall •	AD2: Manufacturing, Packaging or Shipping Problem AD3: Chemical Problem AD4: Material Integrity Problem AD4: Material Integrity Problem AD5: Optical Problem AD5: Optical Problem AD5: Calibration Problem AD5: Output Problem AD5: Temperature Problem AD5: Temperature Problem AD5: Temperature Problem AD5: Temperature Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication or Flow Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication or Flow Problem AD5: Communication or Flow Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication Problem AD5: Communication or Flow Problem AD5: Communication Problem AD5: Communicatic	
2. Rasson for Recall •	ADE: Manufacturing, Packaging or Shipping Problem ADE: Manufacturing, Packaging or Shipping Problem ADE: Maturial Problem ADE: Machanical Problem ADE: Optical Problem ADE: Calibration Problem ADE: Calibration Problem ADE: Calibration Problem ADE: Temperature Problem ADE: Temperature Problem ADE: Connection Problem ADE: Problem ADE: Connection Problem ADE: Probl	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Manufacturing, Packaging or Shipping Problem ADD: Maturial Problem ADD: Maturial Problem ADD: Optical Problem ADD: Optical Problem ADD: Calibration Problem ADD: Computer Software Problem ADD: Communication or Flow Problem ADD: Communication Problem ADD: Communication or Flow Problem ADD: Problem ADD: Problem ADD: Problem ADD: Compatibility Problem ADD: Problem ADD: Compatibility Problem ADD: Problem ADD: Compatibility Problem ADD: Compatibility Problem	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Manufacturing, Packaging or Shipping Problem ADD: Chemical Problem ADD: Machanical Problem ADD: Optical Problem ADD: Calibration Problem ADD: Cammunication Problem ADD: Cammunication Problem ADD: Cammunication Problem ADD: Cammunication or Timesmission Problem ADD: Cammunication or Timesmission Problem ADD: Protective Massures Problem ADD: Problem ADD: Problem ADD: Cammunication Problem ADD: Cammunication Problem ADD: Cammunication Problem ADD: Compatibility Problem ADD: Protective Massures Problem ADD: Problem ADD: Protective Massures Problem ADD: Problem ADD: Protective Massures Problem ADD: Problem ADD: Problem ADD: Problem ADD: Compatibility Problem ADD: Problem ADD: Problem ADD: Problem	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Manufacturing, Packaging or Shipping Problem ADD: Maturial Problem ADD: Maturial Problem ADD: Optical Problem ADD: Optical Problem ADD: Calibration Problem ADD: Computer Software Problem ADD: Computer Software Problem ADD: Computer Software Problem ADD: Environmentation Problem ADD: Protective Measures Problem ADD: Problem ADD: Problem ADD: Problem ADD: Compatibility Problem ADD: Compatibility Problem ADD: Compatibility Problem ADD: Installation-Related Problem ADD: Installation-Related Problem	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Chaenical Problem ADD: Chaenical Problem ADD: Machanical Problem ADD: Optical Problem ADD: Calibration or Theorem Problem ADD: Protective Macaurum Problem ADD: Protective Macaurum Problem ADD: Protective Macaurum Problem ADD: Protective Macaurum Problem ADD: Compatibility Problem ADD: Installation-Buildity Problem ADD: Installation-Builed Problem	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Chemical Problem ADD: Chemical Problem ADD: Machanical Problem ADD: Optical Problem ADD: Calibration or Theorem Problem ADD: Calibration or Theorem Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Installation-Fuelality Problem	
2. Rasson for Recall •	 A02: Manufacturing, Packaging or Shipping Problem A03: Channical Problem A04: Maturial Integrity Problem A04: Optical Problem A04: Optical Problem A04: Calibration Problem A05: Calibration Problem A05: Calibration Problem A06: Calibration Problem A07: Calibration Problem A08: Calibration Problem A08: Calibration Problem A08: Calibration Problem A08: Calibration Problem A09: Corput Problem A09: Corput Problem A17: Computer Software Problem A17: Computer Software Problem A17: Communication or Transmission Problem A18: Contractive Maximum Problem A19: Protective Maximum Problem A19: Protective Maximum Problem A19: Compatibility Problem A19: Compatibility Problem A19: Environmental Compatibility Problem A19: Installation-Falaland Problem A19: Installation-Falaland Problem A19: Labelling, Instructions for Use or Transing Problem A19: Labelling, Instructions Problem 	
2. Rasson for Recall •	ADD: Manufacturing, Packaging or Shipping Problem ADD: Chemical Problem ADD: Chemical Problem ADD: Machanical Problem ADD: Optical Problem ADD: Calibration or Theorem Problem ADD: Calibration or Theorem Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Protective Macaurus Problem ADD: Installation-Fuelality Problem	

B. Recall Class Class I :High Blak Class II :Moderate Bisk Class II :Low Risk Class II :Low Risk Class II :Low Risk D. Action to be taken by the Coatomer/User* dd / mm / yyyy
9. Recall Strategy and action to be taken* 10. Action to be taken by the Coatomer/User* 11. Date of recall initiation*
to be taken * 10. Action to be taken by the Customer/User * 11. Date of recall initiation * dd / mm / yyyy
Customer/User *
te distel eutopen)
12. Extansion timeline for O Yes notification affected customers if required.*
13. Estimated Date to complete dd / mm / yyyy recall*
94. Expected date to submit dd / mm / yyyy follow-up report *
Supporting Document
15. Copy of official Recall Communication * * Ze-spiced files will deles all person files * Mahyle files uplied on all-well be file surfaces int of the total spiceled must set exceed 23/08

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. User need to click the ¹ button on question 2 to read about the attention of the Date of commencement of Recall by manufacturer. The pop-up will be displayed as below:

Data of Commencement of Recall will determine the timeframe of notifying the recall activity to MDA and all offected present based on Class of Recall below: Recall Class I - High Slok : within 2 days. Recall Class II - Mutfum Slok : within 3 working days. Fail to comply with the requirements, may ised to enforcement action in accordance to Regulation 7.6 Regulation II of Medical Device (Duties & Ottigations of Establishment) Regulations 2019. However, if additional timeline is required to notify all affected person, the establishment shall notify the Authority in question 12 below.	ATTENTION	1	
Recall Class II - Medium Halc within 3 working days. Becall Class III - Low Halc within 5 working days. Fail to comply with the requirements, may lead to enforcement action in accordance to Regulation 7 & Regulation II of Medical Davkor (Durine & Ottigations of Establishment) Regulations 2019. However, if additional timelina is required to			I affected
Medical Device (Duties & Obligations of Establishments) Regulations 2019. However, if additional timeline is required to	 Recall C 	Jana II – Mudium Rink: within 3 working days.	
	Medical Device	e (Duties & Obligations of Establishments) Regulations 2019. However, if additional timeline is	

IV. User can click the ^① button to get more information about multiple or single file upload. The pop-up will be displayed as below:

➤ Multiple upload files steps

	ple files upload are all					
Ease						
	Example 1					
	Example 3					
	Example 7					
	Cym				×	
	0.00	NoPC > Downloads	~	6 P Seed	h Downleads	
	Organiza w New Yold				H + 0 0	
	· Cultin *				~	
	The PC					
	3 10 Objects	PDF	PDF	PDF		
	Delter					
	E Documents	Example 1	Example 2	Example 3		
	 Downloads Mosts 	~ Earlier this wee	# (130			
	E Prices					
	Vites	PDF	PDF	PDF	PDF	
	1 01(C)					
	= DAM.(D)	Example 4	Example 5	Example 5	Ecomple 7	
	The other	ume Transfe ? The	and T thereis T	All files		
				Open	Cancel	

➤ Single upload file steps

1.	Click "Browse" or "Choose File" button to upload files.
2.	Multiple files upload are allowed but need to be upload at the same
	time.
3.	Re-upload files will delete all previous files.
4	The input field will state how many files user uploaded (Example: 3
	files selected)

6. Declaration

I. Declaration section will be display as below:

Declaration	
I hereby attest that the	information and attachment provided on this reporting is / are correct, completed and current to this date .*
I understand and ackno	wledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document
which is untrue, inaccu	ana or misfeeding.*
Person Responsible	HOSTOM
for the Establishment	
Aub Title	MANAGER
Telephone	0123456789
Email Address	host011@sebumbung.com

- II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.
- III. In this section, the system will display person responsible details which are:
 - > Person Responsible for the Establishment
 - ≻ Job Title
 - ≻ Telephone
 - ➤ Email Address
- 7. Button Section.
 - I. This section displays all buttons in the Notification Report.



II. Click button to go back to the previous page. There will be two (2) types of pop-up that will be display as below:

Back Confirmation Pop Up	
Back Confirmation	Click "Yes" button
Are you sure to go back to the previous page?	2
Click "No" 3	No Yos

- ➤ Back Confirmation pop-up.
 - If the question Table of Affected Device Details in Section C has been filled, this Back Confirmation pop-up will be displayed.
 - Click the ^{Yes} button to go back to the next page.
 - Click the
- button to stay on the same page.

Draft Confirmation	Click "Save a Draft" button
Changes you make will be lost if you navigate	-
you want to leave this page AND SAVE AS DR	APT7 6

Draft Confirmation pop-up

- If the question Table of Affected Device Details in Section C is still not filled, this Draft Confirmation pop-up will be displayed.
- III. Click the clear button to clear all the information in the report except the default value.
- IV. Click the Preview PDF button to view the report in Portable Document Format (PDF) format.
- V. Click the Submit Notification button to submit the notification report. This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:

Are you sure to submit the application? Close Submit Notification	Submit Confirmation			×
Close Submit Notification	Are you sure to submit the appl	ication?		
		Close	Submit Notification	

5.3.2 Follow-Up Report

a. Click the **□** Follow-Up Report button to create Follow–Up report and the Follow–Up page will be displayed as below:



* Section E - Pollows	Section E : Follow-Up Report Section	
1. Has the Recall commo been sort to all effected		
	2. Table of Affected Person [®] (Entributions may devoted if the samples could be a given the section) 1. Interplane 2: Touplan for Table of Atlanced Persons do ± 1. Example 2: Example for Table of Atlanced Persons do ±	
*	Athented Personal Continuent User Quantity Milented No. Tables of Athented Persons to display	
	Trai 0	
	Silk / Acts Saturdar Research	
Declaration 3	Declaration	
 Thereby attest that the 	information and attachment provided on this reporting is / are correct, completed and current to this date .*	
I understand and ackn	owledge that is an offence-under Section 76 of Act 727, to make sign or furnish any declaration, or other document	
which is untrue, inacco	rate or minimading *	
Person Responsible	HOST 08	
for the Establishment		
Job Title	MANAGER	
Telephone	0023456705	
Email Address	head/01@selumburg.com	
	Button Section	
	Back Chair Premium POF Subsect Follow-Sp	Π

- 1. View Notification Report
 - I. Click to display the submitted Notification Report.
- 2. Click the Section E : Follow-Up Report Section
 - I. Section E will be display as below:

		(Affected Person*		
		nglate encoil file-it uplend at given file se e for Table-of Adhented Person she 🛓	rties)	
		för Table of Afflected Person dis 🛓		
Ne.	Affected Person/ Contemen/U	har i	Generally Alfordual	

Nothing anisoted +	
dd i ron, l yyyy	
dal i mon i yepye	
Supporting Document	
REPORTED The filter and excluded. * It replace filter with them of periods filter. * Multiple filter spinal are directed for the maximum one of the total spinals in mot are around 2018.	
	dd f ann / yppy dd f ann / yppy Supporting Decarater €

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Table of Affected Person:

-0-	Affected Person Section	
	2. Table of Affected Person* (Establishment may download the template excel file & upload at give 1. Template : Template for Table of Affected Person.uks	
	2. Example 🖪 : Example for Table of Affected Person.xi	Template for Table of Affecte Person
No.	Affected Person/ Customer/ User	Quantity Affected
	No Table of Affected Person to display	
	Total	0
	Click "Add Details of Affected Person " button	Edit / Add Details of Affected Person

- > The Table of Affected Person will be displayed as above.
- ➤ There are two (2) template for Table of Affected Person that user can download which are:
 - Example for Table of Affected Person
 - Template for Table of Affected Person
- Users are required to use the template provided to upload it in the table.
- > By clicking Edit / Add Details of Affected Person button, the system will

display Details of Affected Person page shown as below:

	Table of Affected	Person • 0	
	(Establishment may download the template ex-	cel file & upload at given file section)	
	 Template 2 : Table of Ad Example 2 : Example for Table 		Upload File Section
1. Upload file:	Broase No file selected. *Re-gload Se will debre di previou adresation	-	Import File
		2	Uploaded File Section
2. Uploaded file of person :	# 2 Template for Table of Affected Per #	non (MDA_Recall_P0203_9299990_	2022) (PSJgpgM2).ste
No.	Affected Person/ Customer/ User	Quantity Affected	Action
t	Company ABC Sdn. Bhd.	Action Button	Edit Delete
	Total	100	
	Click	• "Next" button	

In the Upload File Section, users can choose the file that needs to be uploaded by clicking Choose File button and

button will be enabled after the user chooses the

file. Then click button to import the file in the table.

- In the Uploaded File Section, it will display the file that the user uploads.
- \succ In the Action column, it has two (2) button that user can use:
 - User can click **Edit** button to update the affected person in the table and the system will display the popup to update the details of affected person shown as below:

Edit details of affected devices
Affected Person/ Company ABC Sdn. Bhd. Customer/ User.
Quantity Affected: 100 Click "Clear" button 2 3
Click "Close" button 1 Close Clear Update
Click the close the population to close the population
 Clear button to clear all the information.

- Click the ^{Update} button to update the information.
- User can click the **Delete** button to delete the information from the table.
- Click the Next button to back to the previous page section E.
- VI. The updated Table of Device Details will be displayed in Section E as shown below:

2. Table of Affected Person* (Establishment may download the template excel file & upload at given file section) 1. Template ∰ : Englate for Table of Affected Person.sis ▲ 2. Example ∰ : Ensample for Table of Affected Person.sis ▲			
No.	Affected Person/ Customer/ User	Quantity Affected	
1.	Company ABC Sdn. Bhd.	100	
	Total	100	
		Edit / Add Details of Affected Person	

- VII. Click Edit / Add Details of Affected Person button if users want to edit add details of the affected person.
- VIII. User can click the ^① button to get more information about multiple or single file upload. The pop-up will be displayed as below:
 - > Multiple upload files steps

2. 600	("Browse" iple files upload a	re allowed but need to	be upload at th	e same time show	wn as below.	
Exa	nple:					
	Example 1					
	Example 3					
	Example 7					
	😨 Cyan				×	
		> ThicPC > Downloads	~	6 P Seed	- Downlands	
	Organiza w N	kw falder			H + 0 0	
	Condition This PC				Î	
	3 10 Objects Deletep Decements	PDF Exercise 1	PDF Grangle 2	PDF Example 3		
	- Downloads	~ Earlier this wee	st (13)			
	👌 Masia					
	an Peters			_		
	Volue:	PDF	PDF	PDF	PDF	
	= 05(C) = 0404(D)	Exempte 4	Example 5	Example 5	Ecompile 7	
	- mar.(c)	×				
		Renewe Transfel? the	ample 11 'Example 21	- All Files	v	
				Open	Cancel	

3. Declaration

I. Declaration section will be display as below:

eclaration	
Thereby attest that th	e information and attachment provided on this reporting is / are correct, completed and current to this date .*
] Lunderstand and ackr which is untrue, inacc	nowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document surate or misleeding.*
erson Responsible or the Establishment	HOET OF
ob Title	NAMAGER
olaphona	0123456799
mail Address	host0118esburrburg.com

- II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.
- III. In this section, the system will display person responsible details which are:
 - a. Person Responsible for the Establishment
 - b. Job Title
 - c. Telephone
 - d. Email Address
- 4. Button Section
 - I. This section displays all buttons in the Follow-Up Report.



II. Click button to go back to the previous page that will be display as below:

Back Confirmation 🚺 🔳	Back Confirmation Pop Up	×
Are you sure want to back?		Click "Yes" button
	Click "No" 3 button No	Yes

- Back Confirmation pop-up.
 - Click the button to go back to the next page.
 - \circ Click the button to stay on the same page.
- III. Click the button to clear all the information in the report except the default value.
- IV. Click the Preview PDF button to view the report in Portable Document Format (PDF) format.
- V. Click the ^{Submit Follow-Up} button to submit the follow-up report.This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:

Submit Confirmation			x
Are you sure to submit the applicatio	n?		
	Close	Submit Follow-Up	

5.3.3 Final Report

a. Click the **EFinal Report** button to create Final report and the Final page will be displayed as below:

View Notification an	orm (Final) CTION View from small be aread automatically as you make progress on the browser Please be cautions with your case details. d Follow-Up Report Eles if you do not want to submit the report yet. art form (Notification & Follow Up)
✓ Section F : Final Report Section	2 Section F : Final Report Section
1. Has the Rocall exercise been complete*	YesNo
2. Status of the device •	Returner to manufacturer Disposed Consumed Other (specify)
3. The method of disposal for the recalled products*	
4. Final risk evaluation (Vine if different from the initial risk evaluation)	
• Bection G : Others Information	3 Section G : Others Information
1. Seconda	
2. Supporting Document	Errors No. First induction. * Re-place film will dation all province film. * Maligin film spinel are allowed but the wanteens one of the total spineled war out around 2028

-	
Declaration	Declaration
D hereby attest that the inform	nation and attachment provided on this reporting is / are correct, completed and current to this date .*
 I understand and acknowledg which is untrue, inaccurate or 	ge that is an offenoe under Section 76 of Act 737, to make sign or furnish any declaration, or other document r misleading.*
Name of Reporting Person	HOGT OM
Job Title	MANAGER
Talephone	0/23456799
Email Address	haat019@websandsung.com
	5 Button Section
	Back Char Preview FDF School Find

- 1. View Notification and Final Report
 - I. Click and Follow-Up Report.

to display the submitted Notification

- 2. Section F : Final Report Section
 - I. Section F will be display as below:

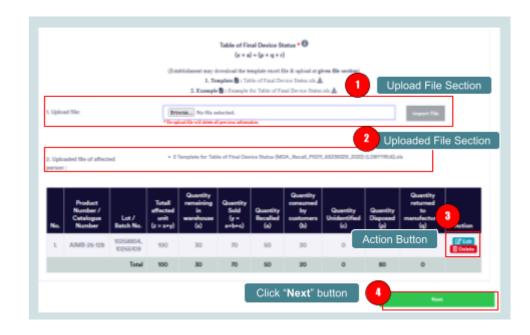
 Section F : Final Report Sec 	tion
1. Has the Rocall exercise been complete ⁴	 Yes No
2. Status of the device *	Returner to manufacturer Disposed Consumed Other (specify)
3. The method of disposal for the recalled products*	
 Final risk evaluation (New if different from the initial risk evaluation) 	

5. Proposed action(s) to prevent recurrence of the problem*	
(h	Table of Final Device Status (x + a) = (p + q + r) tablishment may devalued the template excel file & upload at given file section) 1. Template : B Template for Table of Final Device Status.sh. d, 2. Example B : Example for Table of Final Device Status.sh. d,
Product aff Number / Lot / Catalogue Batch	otall Guantity remaining in Guantity Guantity Guantity Guantity (r = (x)) (x) (x) (x) (x) (x) (x) (x) (x) (x
Total	0 0 0 0 0 0
7. Justification on total quality of unidentified device Size of opticality	Add Final Device Statur
B. Evidence of returning effected device to the manufacturer	Supporting Document
9. Evidence of disposal process	#Torest No Fires selected. * Koupbul file will adde of previou file. *Milgin file updat are alread both maximum size of the total uploaded most not exceed 10x8
10. Evidence of device consumed	Brown No Fires selected. * Respirat files will adde of prevent file. * * Midgle files uplead are directly to the maximum size of the total upleaded must not accord 300.00 *
11. Health risk assessment report Over it different two tested risk ersteniel	# Targetyse No Files selected. * Far-spinel film will defen all pervises film. * Shiliphe film uplead are allowed by the maximum size of the total upleaded read not exceed 200.00

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Table of Final Device Status:

-0	Affec	ted Per	son Sect		untice Status				
		(Tata			(p+q+r)*				
		(Line	1. Template B	: Template for To	able of Final Devis Ale of Final Devis	on Status, alla 🛦		e for Tab evice Sta	le of Final atus
Product Number / Catalogue No. Number	Lot/ Batch No.	Totall affected unit (z = x+y)	Quantity remaining in warehouse (x)	Quantity Sold (y = s+b+c)	Quantity Recalled (a)	Quertity consumed by customers (b)	Guantity Unidentified (c)	Quantity Disposed (p)	Quentity returned to manufacturer (q)
			No Ta	ble of Final De	vice Status to o	Sepley			
	Total	0	0	0	0	0	0	0	0
¢						tails of f us " butto	in team	3 Edit / Add	>

- > The Table of Final Device Status will be displayed as above.
- There are two (2) template for Table of Final Device Status that user can download which are:
 - Example for Table of Final Device Status
 - Template for Table of Final Device Status
- Users are required to use the template provided to upload it in the table.
- ➢ By clicking Edit / Add Final Device Status button, the system will display Details of Final Device Status page shown as below:



> In the Upload File Section, users can choose the file that needs

to be uploaded by clicking Choose File button and

button will be enabled after the user chooses the file. Then click

Import File

button to import the file in the table.

- In the Uploaded File Section, it will display the file that the user uploads.
- > In the Action column, it has two (2) button that user can use:
 - User can click **C** Edit button to update the affected person in the table and the system will display the popup to update the device detail status shown as below:

Edit Device Details Status		
1. Product Number / Catalogue Number:	AIMB-26-128	
2. Lot / Serial No:	10258804, 10265109	
3. Quantity remaining in warehouse: (x)	30	0
4. Quantity Recalled: (a)	50	0
5. Quantity consumed by customers:(b)	20	0
5. Quantity Unindentified: (c)	0	0
7. Quantity Disposed: (p)	80	0
8. Quantity Returned to Manufacturer: (q)	0	0
9. Total affected unit: (z=x+y)	100 * Auto Sum based on user input	
10. Quantity sold: (y=a+b+c)		Update" utton
Click "Close" button		3 state
Click the Close b	outton to close the	popup.
Clear b	utton to clear all th	ne inform

- Click the ^{Update} button to update the information.
- User can click the **Delete** button to delete the information from the table.
- Click the Next button to back to the previous page section F.
- IV. The updated Table of Final Device Status will be displayed in Section F as shown below:

			1. Tes	may deveniend the t aplate 🖥 : Templat ample 🖥 : Example	e for Table of Fis		sto 👗		
No.	Product Number / Catalogue Number	Lot/ Butch No.	Totall affected unit (z = x+y)	Quantity remaining in warehouse (x)	Quantity Sold (y = a+b+c)	Quantity Recalled (a)	Quantity consumed by customers (b)	Quantity Unidentified {c)	Quantity Disposed (a)
٤. /	AIMB-26-128	10258804, 10265109	100	30	70	60	20	0	80
		Total	100	30	70	50	20	0	80

V. Click Edit / Add Final Device Status button if u affected person.

button if users want to edit add details of the

- VI. User can click the ⁽ⁱ⁾ button to get more information about multiple or single file upload. The pop-up will be displayed as below:
 - ➤ Multiple upload files steps

			be upload at the			
mple:						
Example 1 Example 3						
Example 7						
Complete /					×	
	- Thurs	> Downloads	÷	6 P Seed	h Downloads	
Organics # N	lew folder				H + C 0	
Condition	<u>^</u>				~	
The PC						
30 Objects		PDF	PDF	PDF		
Deitte		Example 1	Example 2	Example 3		
Documents		Earlier this week		Company a		
2 Maria						
an Peters						
Volume 1		PDF	PDF	PDF	PDF	
1 (05-(C)		Example 4	Example 5	Example 5	Ecomple 7	
- DAM.(D)	~	Complete a	trange 3	Compile a	Comple ?	
	file name	Transfe 71 the	regile 1" "Exemple 2"	- All Files	~	
				Open	Cancel	

3. Declaration

I. Declaration section will be display as below:

eclaration	
Thereby attest that th	e information and attachment provided on this reporting is / are correct, completed and current to this date .*
	nowledge that is an offenoa under Section 76 of Act 737, to make sign or furnish any declaration, or other document
which is untrue, inacc	surana or misleading.*
erson Responsible	HOSTOM
or the Establishment	
lob Title	MANAGER
alaphona	0123456789
mail Address	host0118seburdoung.com

- II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.
- III. In this section, the system will display person responsible details which are:
 - Person Responsible for the Establishment
 - > Job Title
 - ➤ Telephone
 - ➤ Email Address
- 4. Button Section
 - I. This section displays all buttons in the Follow-Up Report.



II. Click button to go back to the previous page that will be display as below:

Back Confirmation	Back Confirmation Pop Up	×
Are you sure want to back?		Click "Yes" button
	Click "No" button 3 No	2 Yes

- ➤ Back Confirmation pop-up.
 - Click the button to go back to the next page.
- III. Click the button to clear all the information in the report except the default value.
- IV. Click the Preview PDF button to view the report in Portable Document Format (PDF) format.
- V. Click the ^{Submit Follow-Up} button to submit the follow-up report. This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:

mit Final
5

5.4 VIEW RECALL REPORT

a. Click the **View** button to view the reporting and the view page will be displayed as below:

View Report Medical Device Recall Form					
Section A: Medical Device Recall Report Form					
1. MDA Recall Reference Number MDA/Recall/P0211-65238329-2022					
2. Recall Initiated by	Authority (Mandatory Recall) MDA Ref No: try auto save 38920660-06ab-42b3-be20-872898aaa03c (MDA_Recall_P02H_66238329_2022) (cPw7Bobb.pdf				
3. Type of Report	Final				
Section B : Establishme	er Dutails				
1. MDA Establishment	Joense No. KP-HOSTOff				
2. Name of establishme	nt Medical Device Authority Development Team (ICT)				
3. Establishment Addre					
4. Contact Person Nam	e HOST 011				
5. Job Title	MANAGER				
6. Tel No.	0123456789	0123456789			
7. Fax No.	0123456789	0123456789			
8. Email Address	host0118jsebumburg.com	host011@vebumbung.com			
9. CAB Name	CARE CERTIFICATION INTERNATIONAL(M) SDN.BHD				
	nformation and attachment provided on this reporting is / are correct, completed and current to this date . eledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document are or misleading. HOGT Off MANAGER 01224667389				
Email Address	hostOff@wdburburg.com Click "Prev PDF" but 2				
	Click "Back" button	OF			

- 1. View the Recall Report.
- 2. Click the button to go back to the previous page.
- Click the Document Format (PDF) format (Refer to <u>5.5 PREVIEW PDF</u>).

5.5 PREVIEW PDF

5.5.1 Preview Recall Report

a. There are two (2) types of Preview PDF:

1. Preview PDF for Draft Report is shown as below:

Medical Device					
Medical Device Recall Report					
MDA Recall Reference Number. MDA/Recall/P02t1-65238329-2022					
Section A: N	Medical Device Recall Report Form				
1. Recall Initiated by	Authority (Mandatory Recall) MDA Ref No: try auto save • 3920560-06ab-42b3-(rc20-rc209RaasOc (MDA_Recall_P0211-rc208229_2022) (cPwYlOqb).pdf				
2. Type of Report	Ct				
Sec	ion B : Est : Ed. more Deta 1				
1. MDA Establishment License No.	K7440ST011				
2. Name of establishment	14-5ical Device Authority Development Team (ICT)				
3. Establishment Address	011, JALAN CYBERIA 1, CYBERJAYA63000, SELANGOR				
4. Contact Person Name	HOST 011				
5. Job Title	MANAGER				
6. Tel No.	0123456789				
7. Fax No. 0123456789					
8. Email Address	host011@sebumbung.com				
9. CAB Name CARE CERTIFICATION INTERNATIONAL(M) SDN.BHD					

- I. The Declaration Section will not be included in the Preview PDF for Draft Report.
- 2. Preview PDF for Submitted Report.

Medical Device Recall Report					
MDA/Recall/P0177-71029181-2022					
Section A: Medical Device Recall Report Form					
1. Recall initiated by	Establishment (Voluntary Recall)				
2. Type of Report	Final				
MDA Establishment License No.	Section B : Establishment Details				
	Section B : Establishment Details KP-HOSTOH Medical Device Authority Development Team (ICT)				
2. Name of establishment	KP-HOSTOII				
2. Name of establishment 3. Establishment Address	KP-HOST011 Medical Device Authority Development Team (ICT)				
2. Name of establishment 3. Establishment Address 4. Contact Person Name	KP-HOSTOII Medical Device Authority Development Team (ICT) 011, JALAN CYBERIA 1, CYBERIAYA63000, SELANGOR				
2. Name of establishment 3. Establishment Address 4. Contact Person Name 5. Job Title	KP-HOSTON Medical Device Authority Development Team (ICT) ON, JALAN CYBERIA 1, CYBERIJAY A63000, SELANGOR HOST 011				
2. Name of establishment 3. Establishment Address 4. Contact Person Name 5. Job Title 6. Tel No.	KP-HOST011 Medical Device Authority Development Team (ICT) 011, JALAN CYBERIA 1, CYBERIAYA63000, SELANGOR HOST 011 MANAGER				
1. MDA Establishment License No. 2. Name of establishment 3. Establishment Address 4. Contact Person Name 5. Job Title 6. Tel No. 7. Fax No. 8. Email Address	KP-HOST011 Medical Device Authority Development Team (ICT) 011, JALAN CYBERIA 1, CYBERUAYA63000, SELANGOR HOST 011 MANAGER 0123466789				

5.6 EDIT REPORT

5.6.1 Edit Notification Report

a. A part of the edit Notification Report page will be shown below.

Date of report	05/04/2022	
Date of commencement of ecall by manufacturer *	dd / mm / уууу	
Did the Recall arise due to n adverse incident? •	○ Yes ○ No	
. Did this adverse incident ccur in Malaysia? •	• Yes • No	
Has the adverse ovent been aported to MDA? *	YesNo	

- 1. Users can update all information in this report.
- 2. The process to submit the updated report will be the same as submitting a new report. (Refer to <u>5.3.1 Notification Report</u>).

5.6.2 Edit Follow-Up Report

a. A part of the edit Follow-Up Report page will be shown below.

3. List of impacted countries (Note if any and user may choose more than 1 creatry.)	Nothing selected Selected countries: • Algeria • Barbados • Belarus	
4. Proposed date of completion of Recall in Malaysia * (Nor Complete reviewal product from the market)	22/04/2022	
5. Expected date to submit final report to the Authority *	dd / mm / yyyy	
6. The method of quarantine and segregation of recalled products *		

- 1. Users can update all information in this report.
- 2. The process to submit the updated report will be the same as submitting a Follow-Up report. (Refer to <u>5.3.2 Follow-Up Report</u>).

5.6.3 Edit Final Report

a. A part of the edit Final Report page will be shown below:

	Q Yes
1. Has the Recall exercise been complete •	
	Date recall completed O6 / 04 / 2022
	○ No
2. Status of the device *	Returner to manufacturer
	Disposed
	Consumed
	Other (specify)
3. The method of disposal	test
for the recalled products *	

- 1. Users can update all information in this report.
- 2. The process to submit the updated report will be the same as submitting a Final report. (Refer to <u>5.3.3.Final Report</u>).

5.6.4 Return from MDA

a. A part of the edit Return from MDA Report page will be shown below:

Section F : Final Report Section		
1. Has the Recall exercise been complete	Yes No	Remark: No
2. Status of the device *	Returner to manufacturer Disposed Consumed Other (specify) Remark section	• Remark: No
3. The method of disposal for the recalled products *	Testing	• Remark: No
4. Final risk evaluation (Note: if different from the initial risk evaluation)	N/A	Remark: Yes
5. Proposed action(s) to prevent recurrence of the problem *	Testing	Remark: Yes

Declaration					
I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date .* I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*					
2. Person Responsible for the Establishment	HOST 011				
3. Job Title MANAGER					
4. Telephone 0123456789					
5. Email Address	host011@sebumbung.com				
	Button Section 2 Back Preview PDF Submit Report				

- 1. Users can only update the information that has a 'No' remark in this report.
- 2. Button section.
 - I. This section displays all buttons in the Notification Report.



II. Click button to go back to the previous page. The pop-up will be display as below:

	Back Confirmation
	Are you sure want to back?
	Click "No" 3 No Yes
	Back Confirmation Pop-up.
	 Click the yes button to go back to the previous page.
	• Click the button to stay on the same page.
111.	Click the button to view the report in Portable Document Format (PDF) format. (Refer to <u>4.5.1 Preview Recall</u> <u>Report</u>)
IV.	Click the Submit Report button to submit the updated report. This button will be enabled if the user tick the checkbox in the

5.7 DELETE REPORT

a. Delete report only can be made for Draft Notification Report .

Declaration section.

b. Click the **Delete** button to delete the Draft Notification report and the pop-up will be displayed as below:

	Delete Form	Delete Form		Click " Delete " button	
	Are you sure v	Are you sure want to delete the form?		button	2
	- 1	Click " Cancel " button	0	Cancel	Delete
1. Clic	k the Cancel	button to close	the delet	e pop-up	
2. Clic	k the Delete	button to delete	the Notif	fication re	eport.

5.8 OVERDUE REPORTING

a. List of Recall Overdue Reporting Table will be display as below:

	Reporting Table		Overdue Reporting	Table (4)		Closure	Reporting Table (0)
				Table Filter	ing 🚺	0 %	archQ
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (del/mm/vol) Action Butto	Reporting Stans	Status	Action
t.	MDA/Recall /P0189-34155688-2022	MEDICAL TESTOHB		Overd 18/03/2022		Almost Overdue	i⊞ Log
2.	MDA/Recall /P0197-75458948-2022	MEDICAL TESTONC	-	26/02/2022	Follow Up	Overdue	i≣ Log @ View Ē Extend Date (0/2)
3.	MDA/Recall /PX0179-10699735-2022	MEDICAL TESTOND	13/02/2022 -	Action Button 15/03/2022	(Overdue) Notification	3 Overdue	i≣ Log @ View
4.	MDA/Recall /P0188-96321595-2022	MEDICAL TESTONC		23/06/2022	Follow Up	Overdue	E Log Ø View Extend Date (V/2)

1. Table Filtering shown as below:



I. User can click the icon to get more information related to table filtering and the pop-up will be displayed as below:

formation	>
1. Type any keyword:-	
 Recall Reference Number 	
 Date of Reporting (yyyy-mm-dd) (Eg: 2020-01-01 	0
 Due Date for Next Reporting (yyyy-mm-dd) (Eg: 	2020-01-01)
Medical Device Name	
 Status Report 	
Reporting Stage	
2. Click the search icon button ($\fboxtimestical Q_k$) to find the report	٤.
	Close

Click the × button or button to close the pop-up.

- II. Enter any related keyword (based on information given).
- III. Click the \bigcirc icon and the system will display the result.
- 2. Action Button for Overdue Status:
 - I. Click the View button to view the report. (Refer to <u>5.4 VIEW</u> <u>RECALL REPORT</u>)
 - II. Click the **button** to view the reporting log and the pop-up will be displayed as below:

No.	Date	Stage	Status	Officer
4	21/03/2022 08:51:59	Overdue	Recall Follow-Up report are Overdue	System
3	02/03/2022 10:07:50	Draft	Recall Follow Up report has been saved as draft.	HOST 0
2	25/02/2022 11:11:02	Submitted	Recall Notification Report has been submitted.	HOST OF
1	25/02/2022 08:52:11	Draft	Recall Notification report has been saved as draft.	HOST 0

- \succ Click the **Close** button to close the pop-up.
- III. Click the Extend Date (0/2) button to request extension time and the pop-up will be displayed as below:

**REMINDER: Establishmen one (1) application.	t can request to extend the date up two (2) times only for
Request for extension	🔿 30 days
time:*	🔿 90 days
	🔿 120 days
Justification*	
	h

- User are required to fill in all fields that marked with an asterisk (*).
- \succ Click the button to clear all the information.
- Click the confirm button to submit the request for extension time.
- 3. Action Button for Almost Overdue Status:
 - I. Click the View button to view the report. (Refer to <u>5.4 VIEW</u> <u>RECALL REPORT</u>)
 - II. Click the **i**log button to view the reporting log and the pop-up will be displayed as below:

No.	Date	Stage	Status	Officer
4	21/03/2022 08:51:59	Overdue	Recall Follow-Up report are Overdue	System
3	02/03/2022 10:07:50	Draft	Recall Follow Up report has been saved as draft.	HOST OF
2	25/02/2022 11:11:02	Submitted	Recall Notification Report has been submitted.	HOST OF
1	25/02/2022 08:52:11	Draft	Recall Notification report has been saved as draft.	HOST OF

- III. If the report status is Almost Overdue, user have two (2) actions to choose which are:
 - Click the Center button to continue the report and submit the report before Overdue (Refer to <u>5.6 EDIT</u>).
 - Click the Extend Date (0/2) button to request extension time and the pop-up will be displayed as below:

"REMINDER: Establishment me (1) application.	can request to extend the date up two (2) times only for
Request for extension	30 days
lime:*	90 days
	 120 days
Justification*	
	li li
Justification*	

- User are required to fill in all fields that marked with an asterisk (*).
- Click the button to clear all the information.
- Click the **confirm** button to submit the request for extension time.

5.9 CLOSURE REPORTING

a. List of Recall Closure Reporting table will be display as above:

Reporting Table		Overdue Report	ting Table (4)		CI	osure Reporting Table (1)
			Table F	iltering	1 0	Search Q
No. Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (dd/mm/vv)	Reporting Stage	Status	Action
1. MDA/Recall /P0177-71029181-2022	MEDICAL TESTONC	13/02/2022	24/03/2022	ction Buttor Final	Completed	IE Log Ø View Acknowledgement Letter Closure Letter

1. Table Filtering shown as below:



I. User can click the ⁽ⁱ⁾ icon to get more information related to table filtering and the pop-up will be displayed as below:

Information ×
 Type any keyword:- Recall Reference Number Date of Reporting (yyyy-mm-dd) (Eg: 2020-01-01) Due Date for Next Reporting (yyyy-mm-dd) (Eg: 2020-01-01) Medical Device Name Status Report Reporting Stage Click the search icon button (Q,) to find the report.
Click the × button or button to close the

- III. Click the $\[\circ \]$ icon and the system will display the result.
- 2. Action Button

Π.

- I. Click the View button to view the report. (Refer to <u>5.4 VIEW</u> <u>RECALL REPORT</u>)
- II. Click the **button** to view the reporting log and the pop-up will be displayed as below:

No.	Date	Stage	Status	Officer
9	15/02/2022 21:41:03	Submitted	Recall Final Report has been submitted.	HOST OH
8	13/02/2022 21:18:09	Draft	Recall Final report has been saved as draft.	HOST Off
7	13/02/2022 21:14:51	Draft	Recall Final report has been saved as draft.	HOST ON
6	15/02/2022 21:05:42	Draft	Recall Final report has been saved as draft.	HOST OH
5	13/02/2022 20:17:47	Draft	Recall Final report has been saved as draft.	HOST Off
4	13/02/2022 20:15:40	Submitted	Recall Follow Up Report has been submitted.	HOST ON
3	13/02/2022 20:14:24	Draft	Recall Follow Up report has been saved as draft.	HOST OH
2	13/02/2022 20:09:07	Submitted	Recall Notification Report has been submitted.	HOST Off
1	10/02/2022 14:21:31	Draft	Recall Notification report has been saved as draft.	HOST OH

III. Click the Acknowledgement Letter button to view the acknowledgement letter that the system will generate for the user. The acknowledgement letter will be displayed as below:

LOS	VAR URERUNDAN PRANN'I RARATAN Alkari Denin Authority Marat Denin Anthony Marat Denin A	Tel Londonson New (CODESS 000 Award Team <u>annunderson</u> Fred Indelbindigen ny
		erence Number : MDA/Recall/P0177-71029181-2022
	Date	:05/04/2022
HOST 011 Medical Device Authority 011, JALAN CYBERIA 1, 0	y Development Team (ICT) 2YBERJAYA	
Sir/Madam,		
Acknowledgement of M	edical Device Recall.	
Recall by your company		P-2022
Device Name	: MEDICAL TESTONC	
Product No	: MEDICAL TESTORC : GMDTESTFORHOSTORC	
	: GMDTESTFORHOSTORC : 10199454, 10199470, 10208	6%, 10216004, 1022601, 10226098, 10256099, 99, 1026154, 10262338, 10262339, 10262340,
Product No	: GMDTESTFORHOSTORC : 10199454, 10199470, 10208 10236495, 10248188, 102481	616, 10216004, 10223621, 10225098, 10225099,
Product No Lot No Recall Class	: GMDTESTFORHOSTOHC : 10199454, 10199420, 10208 10236495, 10248188, 102481 10205533X	616, 10216004, 10223621, 10225098, 10225099,
Product No Let No Recall Class MDA Registration 2. We hope that your cor affected customers.	: GMDTESTFORHOSTONC 1 1099404, 10009409, 10009 10236495, 1004988, 100491 1020633X : Final Number : HOSTON	ex, to216004, to225031, to225098, to225099, e9, to26m54, to242338, to342339, to342340, eness of the product recall and the communication to your
Product No Let No Recall Class MDA Registration 2. We hope that your cor affected customers.	: GMDTESTFORHOSTORC : 10199404, 10199409, 10208 102064355, 1020495, 10208 : Final : Final Number : HOSTOII npany will monitor closely the effective fort in order to comply with the require	ex, to216004, to225031, to225098, to225099, e9, to26m54, to242338, to342339, to342340, eness of the product recall and the communication to your
Product No Let No Recall Class MDA Registration 2. We hope that your co affected customers. 3. We appreciate your et	: GMDTESTFORHOSTORC : 10199404, 10199409, 10208 102064355, 1020495, 10208 : Final : Final Number : HOSTOII npany will monitor closely the effective fort in order to comply with the require	ex, to216004, to225031, to225098, to225099, e9, to26m54, to242338, to342339, to342340, eness of the product recall and the communication to your
Product No Let No Recall Class MDA Registration 2. We hope that your co affected customers. 3. We appreciate your et Your cooperation I end w	: GMDTESTFORHOSTORC : 10199404, 10199409, 10208 102064355, 1020495, 10208 : Final : Final Number : HOSTOII npany will monitor closely the effective fort in order to comply with the require	ex, to216004, to225031, to225098, to225099, e9, to26m54, to242338, to342339, to342340, eness of the product recall and the communication to your
Product No Let No Recall Class MDA Registration 2. We hope that your co affected customers. 3. We appreciate your of Your cooperation I and v Regards Therk you. Divector	: GMDTESTFORHOSTONC : 1019444, 1019470, 10208 10206458, 1020481 102065832 : Final Number : HOSTON npany will monitor closely the effective fort is order to comply with the require ith thanks. nd Enforcement Division.	ex, to216004, to225031, to225098, to225099, e9, to26m54, to242338, to342339, to342340, eness of the product recall and the communication to your

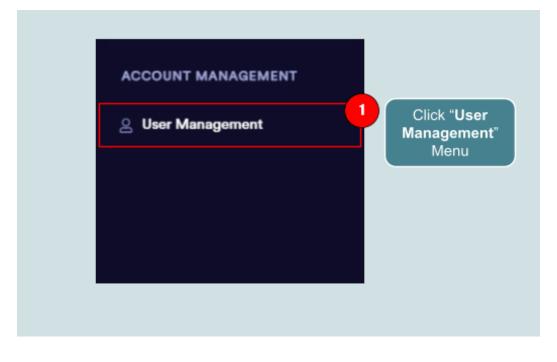
Click the Closure Letter

button to view the closure letter that IV. the system will generate for the user. The closure letter will be displayed as below:

	wice Authority BAN KEDNATAN MALAYDA Masith Malaysis Ins S.Prims Avenue I, Persianan APDS,	The Load Statement Conception of the Load Statement Provide Statem
		Our Reference Number : MDA/Recal/P0177-7029181-2022 Date : 2022-04-05
HDST 011 Medical Device Authority Dev 011, JALAN CYBERIA 1, CYBER		
Sir/Madam,		
With reference to the above, v	ve acknowledge the foll	owing report for recall closure by your company.
MDA Recall Ref. No	: MDA/Receil/POS	7-71029481-2022
MDA Recall Ref.No Device Name	: MDA/Recall/POR : MEDICAL TESTO	
		NC
Device Name	: MEDICAL TESTO : GMDTESTFORHO : 10199464, 101994	NC
Device Name Product No	: MEDICAL TESTO : GMDTESTFORM : 10199464, 101994 10236495, 1024618	90 35T0190 70, 10206616, 10216004, 10223621, 10223698, 10225099,
Device Name Product No Lat No	: MEDICAL TESTO : GMDTESTFORHO : 10199464, 101994 10236496, 1024618 10205533X : Final	90 35T0190 70, 10206616, 10216004, 10223621, 10223698, 10225099,
Device Name Product No Lot No Rocall Class HEA Registration Numb 2. We understand that Medica between 03/02/2022 to 24/03	: MEDICAL TESTO GM/DTESTFC0H+ 1 5099454, 105964 10236495, 1024819 10205533X : Final wr : HOSTOTI I Device Authority Deve 2022. dical Device Authority 1	NC ISTOTHO D, toodeans, toorsood, toozoatry, toosoates, toosoates, a, tookanes, tookitski, tookoates, tookatek, topment Team (ICT) has recalled the above affected device in Development Team (ICT) that the action taken in this recall is
Device Name Product No Lat No Recall Class MDA Registration Nami 2. We understand that Medica between 15/02/2022 to 24/03 3. We would like to inform Me	: MEDICAL TESTO : GMDTESTFORM : COSH446, 105964 : COSH446, 105964 : COSH456, 105964 : COSH57 : Final Mar : HOSTON : Device Authority Deve 2022. dical Device Authority I he level of risk that here	NC ISTOTHO D, toodeans, toorsood, toozoatry, toosoates, toosoates, a, tookanes, tookitski, tookoates, tookatek, topment Team (ICT) has recalled the above affected device in Development Team (ICT) that the action taken in this recall is
Device Name Product No Lat No Recall Class MDA Registration Nami 2. We understand that Medica between 15/02/2022 to 24/03 3. We would like to inform Me appropriately done based on t	: MEDICAL TESTO : GMDTESTFORM : COSH446, 105964 : COSH446, 105964 : COSH456, 105964 : COSH57 : Final Mar : HOSTON : Device Authority Deve 2022. dical Device Authority I he level of risk that here	NC ISTOTHO D, toodeans, toorsood, toozoatry, toozoatras, toozoatras, a, tookanis, tookindk, tookootsa, tookootsa, tookoota, fopment Team (ICT) has recalled the above affected device in Development Team (ICT) that the action taken in this recall is
Device Name Product No Lot No Recall Class MEM Registration Numi 2. We understand that Medica between 13/92/2022 to 24/93 3. We would like to inform Me appropriately done based on 1 Your cooperation I and with th Regards	: MEDICAL TESTO : GMDITESTFORM : COMPARENT, COMPARENT : COMPARENT, COMPARENT : Final err : HOSTON : Device Authority Deve 2002. dical Device Authority i to levice Authority i to levice Authority i to levice Authority i	NC ISTOTHO D, toodeans, toorsood, toozoatry, toozoatras, toozoatras, a, tookanis, tookindk, tookootsa, tookootsa, tookoota, fopment Team (ICT) has recalled the above affected device in Development Team (ICT) that the action taken in this recall is



6.1 USER MANAGEMENT



- a. The Sidebar Menu will be displayed as above:
 - 1. Click **User Management** menu and the system will redirect users and display the user management page.

	User Management					
iveate S	kabuser Create Drafter		te Subuser /			
List O)f Users					Table Filtering
Line o						2
						Search Q
No	Name	Username	Email	Roles	Status	Action
1	ICT Development Team	host010@test	pmax.dev@gmail.com	Supervater	Active	View Preset Password
2	Ainul Mardiah	ainul@dev	zahroh@mda.gov.my	Drefter	Active	View New Paset Paseword If Promote to Sub Account Support Support Delete
3	Zahroh	drafter	zahroh@mda.gov.my	Action But	ton 3	View Reset Password If Denote to Crafter Support Delote
						② View

- b. The User Management page will be displayed as above:
 - 1. Create Subuser / Drafter. (Refer to 6.1.1 Create User)
 - 2. Table Filtering. (Refer to 6.1.2 Table Filtering)
 - 3. Action button
 - Click the View button to view the user information. (Refer to 6.1.3 View)
 - II. Click the **Preset Password** button to reset the password. (Refer to 6.1.4 Reset Password)
 - III. Click the **It Demote to Drafter** button to demote to drafter. (Refer to **6.1.5 Demote to Drafter**)
 - IV. Click the **It Promote to Sub Account** button to promote to subuser. (Refer to **6.1.6 Promote to Subuser**)
 - V. Click the Suspend button to Suspend the user. (Refer to 6.1.7 Suspend)
 - VI. Click the Ounsuspend button to Unsuspend the user. (Refer to 6.1.8 Unsuspend)
 - VII. Click the Delete button to remove / Delete the user. (Refer to 6.1.9 Delete)

6.1.1 Create User

a. There are two type of user which is Subuser and Drafter



1. User can click (i) icon and the pop-up information related to search will display as below:

User Role Information Click "X" button 1 ×			
1. Subuser			
 This User can Create, Edit, View or Delete Reporting This User can submit the Reporting 			
 This User cannot Create, Edit, View or Delete other User 			
2. Drafter			
This User can Create, Edit, View or Delete Reporting			
 This User cannot submit the Reporting This User cannot Create, Edit, View or Delete other User 			
Click "Close" button 2 Close			
Close			
Click × button or button to close the pop			

2. Create Subuser

User Management Testing 1 the Management 1 Date Management Celek - 1 Tester Management Celek - 1 Tester Management Enter Name Tester Username Enter Username	
Create New Valueser CEEck 1 CECK 1 Enter Name Coollip Username CECECK 1 Enter Username	
Click 1 Inter Name tooltip icon Username	
tooltip icon Username	
icon Username	
	Click "Eye" icon button
Enter Email	0
Person Contemporation Contemporation	200
Centre Research 3 Enter Confirm Password	-
Pode* Subser	
Declaration	
B i hereity acknowledge that I have appointed the parton with the same and dotails above, as the establishment's representation	"Submit"
Tick reparting peer marker leases and entries including providing information pervalating to market all entries and entries an	rtals in the system button
Click "Back" button	-

- I. Please enter the Name.
- II. Please enter the Username.
- III. User can click (1) icon and the pop-up information related to the username will display as below:

 Username that has been registered cannot be reused Once Account deleted the username cannot be reused 		2. Once Account deleted the username cannot be reused	Information	Click "X" button
	Click "Close" button 2 Close	Click "Close" button 2 Close	9	
	Click "Close" button 2 Close	Click "Close" button 2 Close		

- IV. Please enter the Email.
- V. Please enter the Password.
- VI. Please enter the Confirm Password.
- VII. Click icon button, to view the password that you enter.
- VIII. Tick declaration checkbox button and the submit button will enable.

IX. Click the button and the system will create a User.



button to go back to the previous page.

3. Create Drafter

	User Manageme	nt	
	Dashioard 3. Das Managerard	> Consile Here Balancer	
	Create New Subuser		
Click 1		1 Enter Name	
tooltip icon	Userrame O	Enter Username	Click "Eye" icon button
	EraP	3 Enter Email	0
	Password*	Enter Password	24
	Confirm Password*	Enter Confirm Password	-
	Role*	Drafter	
	Declaration		_
•	I hereity acknowledg	e that I have appointed the person with the name and details above, as the establishment's representative	Cick Submit
Tick 'Declaratio	on" aware and fully resp	et issues and actions inclusting providing internation pertaining to medical devices and ostabilishment de onable for the information provided by my representative in the system. *	sals in the system button
checkbo button			
		Click "Back" button	East Salest

- I. Please enter the Name.
- II. Please enter the Username.
- III. User can click (1) icon and the pop-up information related to the username will display as below:

Information	Click "X" button
 Username that has been reg Once Account deleted the u 	
Сі	ck "Close" button 2 Close
_	
Click × button or	close button to close the pop

- IV. Please enter the Email.
- V. Please enter the Password.
- VI. Please enter the Confirm Password.
- VII. Click icon button, to view the password that you enter.

b.

- VIII. Click the ^{Submit} button and the system will create a User.
 - IX. Tick declaration checkbox button and the submit button will enable.
 - X. Click the Back button to go back to the previous page.

6.1.2 Table Filtering

a. User can click (i) icon and the pop-up information related to table filtering will display as below:

Inform	ation	I	Click "X" button	1 ×
Search	ning Steps			
	Type any keyword Name Username Email Role Status Click the search in) to find the report	'n
		Click "C	lose" button 2	Close
	×	Close	1	
Click	× button or	but	ton to close the	pop-up.

c. Click $\[\] \]$ icon and the system will display the result.

6.1.3 View

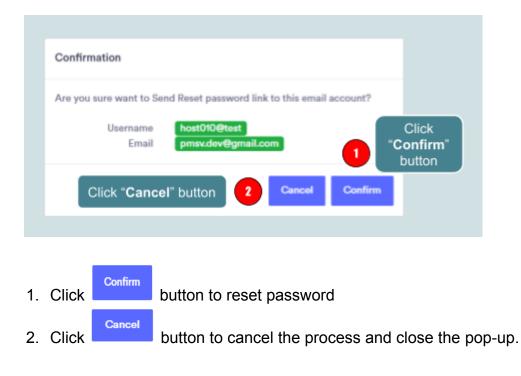
a. Click the **View** button to view the User Information and the view page will be shown as below:

aldrea	of 3 Tour Management 3 United Datain
User	n Details
Nam	e I HOET OT SUBUSER
User	name : hostDTudouserDtext
Ensi	8 : prosidev@grail.co
Role	t (bitmer)
Dec	laretion
0	hereby acknowledge that I have appointed the person with the name and details above, as the establishment's representative in handling any reporting
	regarding post market issues and actions including providing information partaining to medical devices and establishment details in the system. I am
	aware and fully responsible for the information provided by my representative in the system. *
	Click "Back" button 1 👥

b. Click button to go back to the previous page.

6.1.4 Reset Password

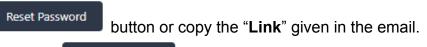
a. Click the **Preset Password** button to reset the password and a pop-up confirmation will appear as shown below:



b. The user will received an email as below:

ŀ	tello!
	ou are receiving this email because we received a password reset equest for your account.
	vord" button
т	his password reset link will expire in 60 minutes.
H	you did not request a password reset, no further action is required.
	hank You, Sincerely, ost Market Surveillance & Vigilance (PMSV)
U	you're having trouble clicking the "Reset Password" button, kindly click on the rl given: https://dev.pmsv.mda.gov.my/dev/pmsv/public/password/reset/e8ebe8 ad26602e4f6e1da0d12ee50a5c3f2f35bdfte3564c64a81f19a6ee80f67email=muha
	amadzafr/%40mda.goz.my
	Copy "Link" Given

1. To continue with reset password, User need to click the



c. After click the system will displayed as below to proceed for the next step:

Notes • Place do not enter the same password is previous • Your password should contain the Following: • Atlasst 10 parcase letters (4-2) • Atlasst 11 Nomber (0-9) • Atlasst 11 special character (n.g. *Id#\$%^&*0.*') Enter Username Username 0 Enter Onfirm Password Confirm Password 0 Enter Confirm Password					
 Please do not enter the same password as previous Your password should contain the Fellowing: Atlaat 11 Dypercase letters (A-2) Atlaat 11 Convercase letters (a-2) Atlaat 11 Special character (e.g. 10885/%*(0r) Enter Username Username Username Enter New Password Confirm Password Click "Reset 	Reset Pa	asword			
Usemane New Password Confirm Password Click "Reset 4 Reset Password		Please do not enter the sam Your password should conta Atleast 1 Uppercase letters (Atleast 1 Lowercase letters (Atleast 1 Special character (r	in the Following: A-2) *==2) *:g. '1@#\$%^&*()_+')		
Click "Reset 4 Reset Password		Username	U		
Click "Reset 4 Reset Password		New Password	2	ল	_
		Confirm Password			vord
			Reset Password		

- 1. Please enter the username.
- 2. Please enter the new password.
- 3. Please enter the confirm password.

Click the Reset Password button. If the reset password is successful the system will redirect the user to the Dashboard (Refer to 2.3 DASHBOARD).

6.1.5 Demote to Drafter

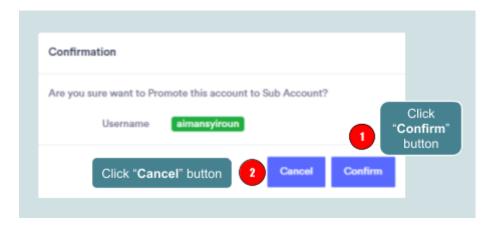
a. Click the **It Demote to Drafter** button to demote the user role from subuser to drafter and The system will show a pop-up confirmation as below:

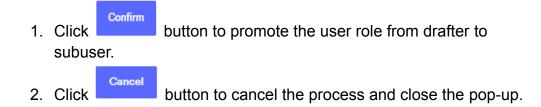
	Confirmation
	Are you sure want to Demote this account to Drafter?
	Username ainul@dev 1 "Confirm" button
	Click "Cancel" button 2 Cancel Confirm
_	Confirm
1.	Click button to demote the user role from subuser to

2. Click button to cancel the process and close the pop-up.

6.1.6 Promote to Subuser

a. Click the **It Promote to Sub Account** button to promote the user role from drafter to subuser and The system will show a pop-up confirmation as below:





6.1.7 Suspend

a. Click the Suspend button to suspend the user account and The system will show a pop-up confirmation as below:

Confir	mation						
Are you	re you sure want to suspend this user account?						
	Username	iman1	3		0	Click "Confirm" button	
	Click "Ca	ancel" but	tton 2	Cancel	Confirm	bullon	

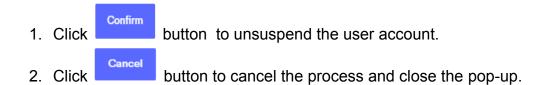
button to cancel the process and close the pop-up. 2. Click

6.1.8 Unsuspend

Cancel

a. Click the Oursuspend button to unsuspend the user account and The system will show a pop-up confirmation as below:

Are you sure want to Unsuspend this user account? Username azanie Click "Confirm" button Click "Cancel" button 2 Cancel Confirm	Confirmation	
		"Confirm"
	Click "Cancel" button 2 Cancel	



6.1.9 Delete

a. Click the Delete button to remove / Delete the user and The system will show a pop-up confirmation as below:

	Delete Confirmation				
			delete this account? d, Username: iman13 cannot be reused. "Delete buttor	9"	
		Click	"Cancel" button 2 Cancel Delete 1		
1.	Click	Delete	button to unsuspend the user account.		
		Caract			
2.	Click	Cancel	button to cancel the process and close t	he pop-	-up.