USER MANUAL FRONT END USER

Medical Device Centralised Online Application System (MeDC@St 2.0)

MODUL UTAMA - DEMONSTRATION & EDUCATION (FRONT END USER)

DISEDIAKAN OLEH :



alaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

LIST OF CONTENTS

1.0 INTRODUCTION	3
1.1 SYSTEM ACCESS	3
1.1.1 CREATE ACCOUNT	4
1.1.2 LOGIN	5
2.0 FUNCTIONS	6
2.1 DASHBOARD	6
2.2 MENU NOTIFICATION REGISTRATION	7
2.2.1 NEW APPLICATION FORM	7
DEMONSTRATION	8
New Application	8
Extension application	18
Post Handling	20
EDUCATION	23
2.2.2 RETURN FOR CHANGES	32

1.0 INTRODUCTION

This manual is prepared for the purpose of operational functions of Medical Device Centralised Online Application System.

MeDC@St is a web-based Online Application System for Notification. It is a centralized system where only one account needs to be created by an applicant to apply for Notification Registration. This module that allows all Notification programme operations to run online and monitoring can be carried out in real time.

1.1 SYSTEM ACCESS

MeDC@st (Medical Device Centralised Online Application System) is developed using web-based method in which it utilizes the internet access via internet server. In order to access Medc@st, user has to key in the URL address onto the internet server as followed:

https://medcast.mda.gov.my

1.1.1 CREATE ACCOUNT

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

For new user need to sign up a new account before login the account. User need to

click Sign Up for new registration.



Sign Up

Complete the form and click to sign up a new account. If you

registration account have success, user need to check the email for confirmation.

1.1.2 LOGIN

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

Username	Pengumuman ANNOUNCEMENT - ABOUT MeDC@St (2017-11-16) New!
Enter username	MeDC@St is a web-basRead More
Password	SEMINAR WITH MEDICAL DEVICE INDUSTRY 2017 (2017-11-10) New! Greetings from the ARead More
Enter password	
Password cannot be blank.	
Sign Up Reset Password FAQ Helpdesk Login	\triangleleft

User has to log into the system using registered Username and its respective

Password. Click Login to proceed.

2.0 FUNCTIONS

2.1 DASHBOARD

Below show the Dashboard page that will appear once Notification Module has logged into the system successfully.



2.2 MENU NOTIFICATION REGISTRATION

Menu Notification Registration has four type of notification which are *Clinical Research Study, Demonstration/Education Purposes* and *Special Access.* However, Clinical Research Study have two types which are Device Study and *Clinical Research Use.* User should click on menu **NOTIFICATION** at left side menu for drop list sub menu Notification module.

2.2.1 NEW APPLICATION FORM



DEMONSTRATION

1)New Application

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.



Next, it will show like below and user have to click "Demonstration" then "New Application Form" to create new application.



The user should click at sub menu **New application form** to apply the registration form for **Demonstration** Purpose. The application form will appear. The figure below shows the application form for applicant fill it. The user should fill all demonstration form. There are three sections which are:

> SECTION A : General information SECTION B : Medical Device Information SECTION C : Attestation and declaration

Section A: General information

Figure below are shown the layout for Section A : GENERAL INFORMATION. User have to fill all the form and that symbol "*" means required field. The user must fill it.

For total date is already show like " Maximum Period - 90 days from date of importation "



This is form for Details of Applicant, user have to fill all the form properly like shown below.

KONT HANDING V2.0	(Southease) Description (C) (Constrained Southease) Southease of Present Responsible of Southease of Present Responsible of	SALACE STATU JOHNER JOHNER SEDAM SEZAMT SEZAMTNN NERLARA NERLARA NERLARA PERLEN PERLEN PERLEN PERLEN PERLEN PERLEN SALAV
	1. MCPumpetSter ¹ ©	A.Designation ** SELANDON ESLANDON EXAMPLE MULADAR * PERSENJ TUAN MULADAR * PERSENJ TUAN MULADAR * PERSENJ TUAN MULADAR * PERSENJ TUAN LUBURA MULADAR * PERSENJ TUAN LUBURA MULADAR * PERSENJ TUAN LUBURA MULADAR * PERSENJ TUAN LUBURA
	Experimenter, Exercises attract. ⁴⁴	
→ Fill a and o	Il the field with proceedings	pperly

Medical Device Authority, Ministry of Health Malaysia

alaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

HORE User just NOTECCION User an ACCOUNT MANAGEMENT	st choose any d tick box	Gon/company is not an "Establis Bishment" according to the defit he type of establishment in Section 2	hment' accord nition under Se Act 737	EN = (1	Application Details SECTION A:GENERAL INFORMATION
O OMLINE ELP +	MANUFACTURER MANUFACTURER MAUTHORISED REPRESENTATIVE DISTRIBUTOR DISTRIBUTOR DISTRIBUTOR DISTRIBUTOR DISTRIBUTOR DISTRIBUTOR	157		After fill all the click "Next" but	form, ton.
	Atready substituted license application (10 Atready abtained establishment license (1) User just cho type and tick	Application Frem.) kerner Hell oose any & box		Ned	•

Section B: Medical Device Information



After user click " Add More Medical Device " and fill all the form, it will be shown like below.



🖉 Update Site Details

For

, users have to tick the checkbox and enter the

Site Details Supplied Quantity since the **Vupdate Site Details** data are extracted from Section A. The value of Supplied Quantity must be less or same with the value of Device Quantity Imported. If users enter the value of Supplied Quantity more than the value of Device Quantity Imported, a pop-message as below appeared and the value of Supplied Quantity will reset same as the value of Device Quantity Imported.



After the user fill all form, users have to click " ▶ " button to the last section.

value of Device Quantity Imported

1

User Manual Front End User - Notification

Medical Device Authority, Ministry of Health Malaysia

Medical Device Centralised Online Application System (MeDC@St 2.0)

Orgenial * New Folder Distance Distance </th <th></th> <th></th> <th> Open -> </th> <th>- 🛧 🧮 + This PC + Dewnlands</th> <th>+ Decuments v[0]</th> <th>Seech Doca</th> <th>ments</th> <th>× </th> <th></th>			 Open -> 	- 🛧 🧮 + This PC + Dewnlands	+ Decuments v[0]	Seech Doca	ments	× 	
Maximum File Size : 300MB Distance Distance <thdistance< th=""> Distance Distanc</thdistance<>			Organize	 New folder 			10 × 1	••	
Maximum File Size : 300MB PUP Only PUP on			~ ^	Name	Date modified	Турн	Size	<u>î</u>	
Maximum File Size : 300MB Supported File Type : PDF Only Upleaded File : - No results found After choose a pdf file, it will shown like below, user can delete and download that file.				21	12/12/2016 3-21 PM	POF File		2018	
Maximum File Size : 300MB OFF The INTENDED UF Status Sta				🗿 Araia	10/4/2016 7:09 PM	POF TEA		625.42	
Maximum File Size : 300MIS Supported File Type : PDF Only Upleaded Files : No results found After choose a pdf file, it will shown like below, user can delete and download that file.				🛃 Apacio	7/5/2016 7:35 PM	POF File		20148	
Maximum File Size : 300MB Supported File Type : PDF Only Upleaded File : No results found After choose a pdf file, it will shown like below, user can delete and download that file.				09ev024	25/4/2016-4/04 AM	POF File		198.42	
Maximum File Size : 300MB If EliCAL DEVICE: SAM Supported File Type : PDF Only If EliCAL DEVICE: SAM It is it i				Siject	29/3/2016 211 PM	POF File		962.10	
Maximum File Size : 300MIS Supported File Type : PDF Only Upleaded File Type : pdf Upleaded Files :- No results found After choose a pdf file, it will shown like below, user can delete and download that file.			- 1	E 3	25/4/2016 3:39 AM	POP File		1,233.48	
Maximum File Size : 300MB with a bit Augurage 4/5/2016 34.64.44 POF The Users 6 Supported File Type : PDF Only OF THE INTENDED UT 1998/e54.46/Augurage 3/5/2016 11:53.04.44 POF The 3.32.18 Image: Supported File Type : PDF Only OF THE INTENDED UT 1998/e54.46/Augurage 3/2/2016 11:53.04.44 POF The 3.32.18 Image: Supported File Type : PDF Only Image: Supported File Type : PDF The				9.1.1	23/4/2016 3-38 AM	POF File		465.48	
Maximum File Size : 300MB Supported File Type : PDF Only Upleved life "Supported File Type : pdf Upleved life "Supported File Type : pdf Vpleved life supported Fi				10.1.1.227.8959	4/5/2016 2:34 AM	POF File		000.00	
Supported File Type : PDF Only	Maximum File Size : 3	300MB	2.5404	12-21-11	24/5/2016 10-40 PM	POP File		2,270.48	nt's l
Supported Files → No results found. After choose a pdf file, it will shown like below, user can delete and download that file. Not <	Supported File Types	OUT THE INTEND	DED US	IStacksAndQueues	10/5/2016 11:53 PM	FOF File		5,752.18	
Vigland Mar Supported File Type: pdf Vigland Mar Supported File Type	supponed mile type th	POP Only		E 15-2hahn	23/4/2016 215 AM	POF File		549.42	
Liptead Me Supported File Type: pdf File same Upleaded Files = No results found. After choose a pdf file, it will shown like below, user can delete and download that file. Not ◄	· ·		· · · ·	R 021	6/5/2016 5:08 AM	POF File		4110 14	
Upteaded Files - No results found. After choose a pdf file, it will shown like below, user can delete and download that file.	LUpload file Suppl	orted File Type : pdf		File name	~	All Files		-	
Vpleaded Files > No results found. After choose a pdf file, it will shown like below, user can delete and download that file. Not 4						Onen			
Upbeaded Files > No results found. After choose a pdf file, it will shown like below, user can delete and download that file. ★ Predoxs			_			- Carlos	- La	Ince	
Votes of Files - No results found. After choose a pdf file, it will shown like below, user can delete and download that file.						open	- u	nos	
After choose a pdf file, it will shown like below, user can delete and download that file.						open		nca .	
After choose a pdf file, it will shown like below, user can delete and download that file.	Unicarfed Files :-					oper		noe	
Anter choose a pointie, it will shown like below, user can delete and download that file.	Uploaded Files :-				-	- Optim			
like below, user can delete and download that file.	Uploaded Files	After choose a	ndffilo	it will shown	7	- Optim		nor	
Fredous	Uploaded Files :- No results found.	After choose a	pdf file,	it will shown	7	dan		nos ,	
Previous	Uploaded Files :- No results found.	After choose a	pdf file,	it will shown		da			
Previous Not -	Uploaded Files :- No results found.	After choose a like below, user	pdf file, r can de	it will shown elete and]				
NO. 1	Uploaded Files :- No results found.	After choose a like below, user	pdf file, r can de	it will shown elete and	\mathbf{F}	- Open			
	Uploaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and					
	Uploaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown lete and]_			N	iest 🕯
	Uploaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				K	let 🕇
	Uploaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown lete and				N	iest 🕇
Uploaded Files -	Upleaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				N	iest 🕈
Uplanded Files -	Uploaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and		- de		N	iest 🔺
Uplanded Files > 129izelandiganun p#	Uploaded Files :- No results found. Previous Uploaded Files :- Uploaded Files :- Uploaded Files :-	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				K	iot 🕈
lybaded Files :-	Upleaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				N	iet 🕈
Uplanded Files :-	Uploaded Files :- No results found. Previous Uploaded Files :- 158adaledQuum.pf	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				N	iot 🔶
Ispinaded Files >	Uploaded Files :- No results found. Previous Uploaded Files :- 159adaledQuom.pdf	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				N	iest 🕈
Nphaded Files > 129acialedQueum.pdf	Upleaded Files :- No results found.	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				K	iest 🕈
Liplanded Files :-	Uploaded Files :- No results found. Previous Uploaded Files :- 159adaledQueun.pdf	After choose a like below, user download that f	pdf file, r can de file.	it will shown elete and				N	iet +

Section C: Attestation And Declaration



After clicking "PREVIEW AND SUBMIT" button, it will display all the section are already complete fill out or not complete like shown below.

		SUTORA, GROUP MURRIED		Ser Longith
		1. Start State Protocol of Research office, Fashing Selection)	: 207-02-08	
		 Eart Data Restored of Recommendation (Particing (ScienceRev)) 	1. 2017-02-08	×
		3. Table Dags Proceeded December 2010, Patholog (education)		
If any lighting	and most commutate	1. Name of Spatiant		
if application a	are not complete,	3. Mill Rev Property		
user can click	"Not Complete"	1. Berlgestine		
	Not Complete	4. Separador Nava		
button to disp	lay what is not	1. Althout O'Department		
complete Lie	alea can view		1	
	SECTION C AFTESTATIONS & DECLARATION			
	Submit o fly can be done if all fields mandatory are complete			
	SECTION C : ATTESTATIONS & DE	CLARATION		Comple
	1. Terms And Conditions	: Yes		×
		h		

User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below. Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

Notification Of Demonstration Application				×
😫 Submit		Ma co	ake sure all is	٦
DEMONSTRATION OF NOTIFICATION	ete 🚽			
SECTION A : GENERAL INFORMATION				Complete
SECTION B : MEDICAL DEVICE DETAILS				Complete
SECTION C : ATTESTATIONS & DECLARATION			⊢	Complete
Submit.	Finally, user of their applicati section is con	an submit on after all nplete.		

After clicking "submit" message alert will be displayed to confirmation of submitted.



If user click "ok", the application status will be changed to "EVALUATION". It will automatically jump to all application page like shown below. Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

	Notification App	Notification Application -					
	DEMONSTRA	TION OF NOTIFICATION	Complete				
	SECTION A 1 G	GENERAL INFORMATION				Complete	
	SECTION B : M	AEDICAL DEVICE DETAILS				Complete	
	SECTION C : A	ATTESTATIONS & DECLARA	TION			Complete	
				<u> </u>		_	
Notification Form App	olication List	l lser can vie	aw that				
Notification Form App ing 1-4 of 4 fizma. Submission ID	Submitted At	User can vie application a	ew that already	Application Status	Action		
Notification Form App ing 3.4 of 4 Hema. Submission ID Searth	Submitted At	User can vie application a filled.	ew that already	Application Status	Action		
Notification Form App ng 1-4 of 4 frema. Submission ID Search DH-20171228-22	Submitted At Search 27-32-2017	User can vie application a filled.	ew that already	Application Status Search EVALUATION	Active Q View		
Notification Form App ing 1-4 of 4 (tema. Subminutee ID Search DH-20171228-22 DH-20171228-21	Submitted At Search 27-12-2017 Not Submitted Yet	User can vie application a filled.	DEMONSTRATION	Application Status Search EWALUNTION URWIT	Active Q.View Q.View Q.View Defents		
Notification Form App ng 1-4 of 4 Hema. Submission ID Search DH-20171226-22 DH-20171226-23 DH-20171226-20	Submitted At Scarch 27-32-2037 Not Submitted Vet Not Submitted Vet	User can vie application a filled.	DEMONSTRATION DEMONSTRATION	Application Status Search EVALUATION DRAFT	Action Q there Q Ten B Colors Q tore Q tore Q tore Q tore Q tore Colors		

2) Extension application

z

Extension application for demonstration can be registered from new application demonstration that have been completely registered. To register

for extension demonstration, user can click button

Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

	20 Conditioneth Constitution Co	-
 номе мотяхалон 	New / Netfodor Lie	
	Notification List	
+ Custom Hade	Strong 12 of 2 terrs.	
Demonstration / Education Purgoous	the submission of submission of submission of submission of the submission submission submission of the submission of the submission submission of the	
Kternandzation		
 Tancial Access 		
* All North Cables (4)	will displayed then	
- HERONY(0)€	click "ok" to proceed	
X ACCOUNT MANAGEMENT		
OMUNE HEP		
	Confirm to make Subsequent?	
	Cancel	

After user click button "Ok", form extension as below will be displayed. User only have permission to update their previous application data at section A (Event Details) and Section B (Site Details).

MEDOS v2.0	Quick Search Q Advance Search		🔳 ENGLISH = 🔺 (10) - NOTE	PICATION TEST - NOTIFICATION TEST -
ев номе 🗸	NOTIFICATION OF MEDICAL DEVICE FOR : (In accordance with Medical Device (Exemption)) Order 2016)	_	
	DEMONSTRATION FOR MARKETING			Application Details
Х АССОЦИТ МАНАСЕМЕНТ -	Please complete all information requested on this form.	(All fields are mandatory unless stated otherwise).		SECTION A: CENERAL
C ONUMERELP +				INFORMATION
	SECTION A: GENERAL INFORMATION			SECTION 8 : MEDICAL DEVICE INFORMATION
	1. Period of Demonstration : * Start Date : *	Start Date : *	Total Day (s):*@	SECTION C : ATTESTATIONS & DECLARATION
	2018-08-18	2018-08-22	4	Q PREVIEW AND SUBMIT
			Maximum Period - RE days from expry of the first exclusion	
	Add Event Details			
	Showing 1-2 of 2 items.			
	Type of Event : -Trade Shev/Jair or enhibition -Presentation / No Explanation Demonstration Location	Demonstration e.g. e Date scher	se provide supporting document wwr.t.brochures from official websile, skde, letter etc.	
	1 EVENT1 KLSENTRAL	2018-08-16 Defer	✓ Update ✓ Update Miner 1,14M8.pdf ✓ Update Ø Delete	

After all the forms are completed, the user must click button "PREVIEW AND SUBMIT" to view and click button "Submit" to submit the application. The alert message will be displayed and user should click "OK" to proceed and "Cancel" to cancel the submitted.

Confirm Submit Application?	×
	Cancel

If user click "OK", the status at application will be changed to EVALUATION.

3) Post Handling

Post Handling can be registered after application in status compete. To

register for post handling, user can click button

Post Handling "

Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

Post Handlin	u.					ж
POST H	IANDLING NOTICE	TO AUTHORITY				User need to fill post
1. Piea	se provide details	on the method used f	or post handling of unregiste	red medical device.		device.
No	ing 1-1 of 1 item. Device Name	Brand/ Model	Manufacturer's Name	Post Method	•	
1	SCOPE	SONY	HISENCE	(not set) + Add Po	est Method	
•	Select file 🍇	upported File Type : p	df	supporting d in pdf type.	ocument	
N	o results found.					
3. Ded 1 here	laration: by declare that:				Us	er click attestation if
C Th out o	ne demonstration of Malaysia.	event is over and all	medical devices involved are	properly disposed of or destroye	d; or exporter CO	nditions.
C Th	e internation pro	rided on this application it is an offence to ma	tion is accurate, correct, con ske sinne or furnish anu daeb	plete and current to this date. I use the second se	inderstand	-

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

Handling	5				
1	SCOPE	SONY	HISENCE	POS LAJU	+ Add Post Method
2. Pleas Suppor	e provide supportin rting Documents ielect file * Sup	ng document relate oported File Type : p	d to the post handling p df Q	rocess which had been u	used.
Uploa	ded Files :-	1			
3. Decla	ration:				
I hereb The out of The and a inaccu	y declare that: e demonstration en f Malaysia. e information prov cknowledge that it arate or misleading	vent is over and all ided on this applica i is an offence to m g as required by Se	medical devices involve ation is accurate, correc ake signs or furnish any ction 76 of Medical Dev	After fill all t information, appear. Use proceed sul handling.	the required , button "save" will er can click it to bmit post
8 5	SAVE				

EDUCATION

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.



Next, it will show like below and user have to click "Education" then "New Application Form" to create new application.



The user should click at sub menu **New application form** to apply the registration form for **Education** Purpose. The application form will appear. The figure below

shows the application form for applicant fill it. The user should fill all education form. There are three sections which are:

SECTION A : General information SECTION B : Medical Device Information SECTION C : Attestation and declaration

Section A: General information

Figure below are shown the layout for Section A : EDUCATION / TRAINING CENTRE DETAILS. User have to fill all the form and that symbol "*" means required field.

MOBCIS van	Continent C Extendiors		🖷 INGLEH - 🔺 [10]-	ACTIVICATION TEXT-INCREMENTION TEXT-
	ALTERNA - BRICHTERN TRAINING (DNTRE DESIGN)			
A SUBJECTION -	1 January Married Romanna *			Application Details
• • • • • •	1 General Same *			BICTOR & HERICALOFUCE BICTOR & HERICALOFUCE
				BETCH C ATTENTIONS & BECAMPTON
	k izvation killingen *			& HORIZAND LANT
		Change 1		
	A Reportment *			
	1 morp.*	1.000		
	1. Person in strange Karsus *	timete.*		
	1 justices ⁴	Same in placements		
		Constant Constant Constant		
		Second Second		
	Fill all the field with properly and correctly.			

This is form for Details of Applicant, user have to fill all the form properly like shown below.

User Manual Front End User - Notification

Medical Device Authority, Ministry of Health Malaysia

Medical Device Centralised Online Application System (MeDC@St 2.0)

MCC (100 100 100 100 100 100 100 100 100 10	CONTINUES CONTINUES		-
	Regulation Company antinan 1 ⁴		
	1. Tringing in a ⁴ B	A final Materia ¹ ©	
Fill al and c	I the field with proceedings	roperly	

After user fill all the form with properly, they have to click " » " button to next section like shown below.

VERSING (und Sand) (C Reserved Sand)	my is not an "Establishment" according to the definition under Section 2 of Act
MOTERCUTON type and tick box Establishment's	ccording to the definition under Section 2 of Act 737, please state : 🔊 Application Details
X ACCOUNT MANAGenerative approach and a second seco	SECTION A1 GENERAL INFORMATION
ORLAR RUP	SECTION 8 : MEDICAL DEVICE INFORMATION
b) status of your establishment license under Act 737	After fill all the form, click "Next" button.
Atrenty admitted timese application (D Application 7 Atrenty admitted timese (Linese No.) User just choose type and tick box	

Medical Device Authority, Ministry of Health Malaysia

alaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

Section B: Medical Device Information

After clicking " 💽 " button at section A, it will display section B like shown below.



below.

User Manual Front End User - Notification

Medical Device Authority, Ministry of Health Malaysia

Medical Device Centralised Online Application System (MeDC@St 2.0)



users have to add first like shown below.

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

EDICAL SITE(DEVICE DETAILS (Repeat a S) DETAILS	Site Name *		
No	Site Name	have to click "Ac	d" button to save	
No	Site Name	have to click "Ac that data. After t below.	ne form, and user d" button to save nat, it will display like	
No No SITE(5) C + Add M	Site Name results found. DETAILS Nore Site Detail	have to click "Ac that data. After t below.	user form, and user d" button to save nat, it will display like User can delete that data.	
No No SITE(S) (+ Add M Showing	Site Name results found. DETAILS Nove Site Detail 1-1 of 1 item. Site Name	have to click "Ac that data. After t below.	the form, and user d" button to save nat, it will display like User can delete that data.	
No No SITE(5) C + Add M Showing No	Site Name results found. DETAILS Nore Site Detail 1-1 of 1 item. Site Name	Ste Address	user form, and user d" button to save hat, it will display like User can delete that data.	

After the user fill all form, users have to click " vert • " button to the last section.

User Manual Front End User - Notification

Medical Device Authority, Ministry of Health Malaysia

Medical Device Centralised Online Application System (MeDC@St 2.0)

	● Open ← → = 个 □ + This PC + Deventeedb	+ Decoments - v [b]	Search Documents	× 	
	Organize * New folder			• • •	
	- Harne	Date modified	Type	54.0	
		12/12/2016 3-21 PM	POF File	24718	
	pi Araia	10/4/2016 7:09 PM	POF File	636.42	
	El Apecto	7/5/2016 1:35 PM	POP File	20140	
	- Di 0994024	25/4/2016-404-AM	PDP Hoe	191.10	
	p Super	20(3)2010-211 PM	PUP 108	1 111 12	
	S 911	23/4/2014 3/28 AM	POF File	45.48	
	10.1.1.227.6999	4/5/2016 2:34 AM	POF File	1.052.62	
E M EDICAL DEVICE: SAM	12-21-11	24/5/2016 10:40 PM	POF Ne	2,270.48	ILET
Maximum File Size : 300MB	13StacksAndQueues	10/5/2016 11:53 PM	FOF File	3,782.48	
Supported File Type : PDF Only	E 15-2haha	23/4/2016 2:15 AM	POF File	549.42	
	 <u> </u>	6/5/2018 5:08 AM	POF File	40110 +-	
	_ + <			2	
Lupload file Supported File Type : pdf	File name:	~	All Files		
			Oran be	Canad	
			obus. 1-		
Related of Plane					
Uploaded Files (-					
Normitstant After choose a pdf	file it will about				
Alter choose a pol	me, it will shown				
	امتده متمامات مت				
like below, user ca					
like below, user ca	in delete and				
like below, user ca	in delete and				
like below, user ca download that file.	in delete and				
like below, user ca download that file.	in delete and			N	est 🔶
like below, user ca download that file.	in delete and			N	lot 🔸
like below, user ca download that file.	in delete and			N	iot 🕈
Iike below, user ca download that file.	in delete and			N	iot 🔶
	in delete and			N	et 🌩
				N	et 🕈
Ike below, user ca download that file.	in delete and			N	et 🕈
	in delete and			N	et 🔶
					iest 🔶
Iike below, user ca download that file.				N	iest 🌩
Ike below, user ca download that file.					iet 🕈
					iet 🕈

Section C: Attestation And Declaration

MCDORS: v20 Franker Incase Incase Incase Incase	CON C : ATTESTATIONS & DECLARATION ON C : ATTESTATIONS & DECLARATION Ne undersigned, heredy attest and declare that: Ne undersigned, heredy attest and declare that: Ne undersigned, heredy attest and declare that: Ne perfection induces of entities application in/ere readical device() according to the definition of "read of perfection and/or seguidy unregistered readical device() according to the definition of "read of perfection and/or seguidy unregistered readical device() according to the definition of Abren	Finally, after user already read, user have to click that button to preview and submit it application.	SEUNA NOTITIERS - PENSEUNA NOTITIERS - Application Details SECTION A: Device, PECENNES SECTION B: MODAL DEVICE PECENNES
User can go to previous page when click this button	In all expert writter supply unregistered medical device() as in Section C only for the purpose stated is shall not use the unregistered medical device() as in Section C on a human or use to provide result or that appropriately table the medical device() The Demonstration Purpose Only. Net for Use On them that comply fully with the terms and conditions in possed in the Acknowledgement on Netflication by an aware that advertising of any unregistered medical device() will properly dispose of or deervoyed or expanded shall write with relevant competent addevice() will properly dispose of or deervoyed or expanded the information, or other document which is earned, instructly prohibited ander Section 44, A shall write with network competent addevice() will properly dispose of or deervoyed or expanded the information, or other document which is earned, instructure or medications in Malaysia, if applies that exact that the unregistered medical device() will properly dispose of or deervoyed or expanded the information, or other document which is earned, instructure or medicating as required by factors in the above terms at the information provided on this application is earned, instructure or medicating as required by factors in the above terms at the information provided on this application is earned, instructure or male and agree to the above terms at the information provided on this application is earned, instructure or medicating as required by factors in the declaration, or other document which is earned, instructure or male and agree to the above terms at the information provided on this application in a count to prove the read and the terms at the information provided on this application in a count to prove the provided by factors in the other and agree to the above terms at the information of the informati	n triba application entip. information to support or reject the patient's diagnosis/treatment ser", the Anthonity. at 737. Able Ein: Royal Multiynian Customs, Atomic Energy Licensel for the distribution of Multiynian Customs, Atomic Energy Licensel for the Authority, referstand and acknowledge that it is an effecte to make signs or Multical Desice Act 2012 (Act 707). of conditions.	K. etc. K.

After clicking "PREVIEW AND SUBMIT" button, it will display all the section are already complete fill out or not complete like shown below.



User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below. Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

Notification Of Demonstration Application			×
😫 Submit		Make	sure all is lete.
DEMONSTRATION OF NOTIFICATION	ete ┥		
SECTION A : GENERAL INFORMATION			Complete
SECTION B : MEDICAL DEVICE DETAILS			Complete
SECTION C : ATTESTATIONS & DECLARATION			Complete
😰 Submit	Finally, user of their applicati section is con	can submit on after all nplete.	

After clicking "submit" message alert will be displayed to confirmation of submitted.



If user click "ok", the application status will be changed to "EVALUATION". It will automatically jump to all application page like shown below. Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

	Notification A	pplication - ATION OF NOTIFICATION	Complete			,
	SECTION A	GENERAL INFORMATION				Complete
	SECTION B	MEDICAL DEVICE DETAILS	5			Complete
	SECTION C :	ATTESTATIONS & DECLAR	ATION			Complete
Matification Form And	licetice the					ה
ing 1.4 of 4 fierra.	Incasion List	User can v	iew that			
Submission ID	Submitted At	application	already	Application Status	Action	
Search	Search	nneu.		Search		
DH4-20171218-22	17-12-2017	NAZIRAH	DEMONSTRATION	EVALUATION	Q,View	
044-20171216-21	Not Submitted Yet	NAZIRAH	DEMONSTRATION	DRAFT	Q.V.ew Vipdate	
DH-20171216-20	Not Submitted Vet	NAZIRAH	DEMONSTRATION	DRAFT	Q, View 🖋 Update	
044-20171214-19	Not Submitted Vet	NAZIRAH	DEMONSTRATION	DRAFT	Q, View 🖌 Update 🔒 Delete	

2.2.2 RETURN FOR CHANGES

If back end user make the process "RETURN FOR CHANGES" to front end user, the status of application will be changed and the Front End User should make the changed at application form that applied.

The figure below shows the application status that changed in front end user.

Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)



After that, user should click at ^{vpdate} to update or make changes at application form. The details of information that user click "NO" at EVALUATION process will be



displayed that shown in the figure below.

Then, user should update the details of application information at the form. The user can edit at detail that changed only.





to submit the application.

Investigational Device Application	×
SECTION B : SPONSOR DETAILS *Sponsor Details Dont Need To Be Filled For Local Sponsor Local Sponsor	or 1
SECTION C : APPLICATION DETAILS	te
SECTION D: ENTRY POINT (Note: For Importation Only)	te
SECTION E : MULTIPLE SHIPMENT	te
SECTION F : ATTESTATIONS & DECLARATION	te
SECTION G : INVESTIGATOR BROCHURE Comple	te
SECTION H : CLINICAL INVESTIGATION PLAN	te
SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP)	te
Extra Information And File Upload	
Submit Click for submitted	•

The status will be changed to EVALUATION again that shown in figure below.

1	IU-20171208-21	22-12-2017	NAZIRAH	INVESTIGATIONAL USE	EVALUATION	QView
---	----------------	------------	---------	---------------------	------------	-------

The user should make the process EVALUATION at back end user.