USER MANUAL FRONT END USER

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

MODUL UTAMA - ESTABLISHMENT LICENSE

DISEDIAKAN OLEH :



Medical Device Authority, Ministry of Health Malaysia

ysia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)

LIST OF CONTENTS

1.0 INTRODUCTION	3
1.1 SIGN UP	4
1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT	5
2.0 NEW REGISTRATION	8
2.1 ESTABLISHMENT DETAILS FORM	10
2.2 PERSON RESPONSIBLE DETAILS	18
2.3 CONTACT PERSON DETAILS	23
2.4 QUANTITY MANAGEMENT DETAILS	28
2.5 ATTESTATION FOR ESTABLISHMENT	31
3.0 RENEWAL APPLICATION	33
4.0 AMENDMENT MINOR	42
5.0 AMENDMENT MAJOR	49
6.0 WITHDRAWAL	56
7.0 SURRENDER	58
8.0 CHANGE OF OWNERSHIP	60

1.0 INTRODUCTION

MeDC@st v.20 (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

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

MCDCOSt v20	MEDICAL DEVICE CENTRALISED	
Username	Pengumuman	1/1
& Enter username	Testing public particles Newl Sense of Tital or e. Read More.	
Password	Test announcement sz (ann-roan) Newl It lived approximate. Read More.	
Enter password		
Sign Up Reset Password FAQ Helpdesk Login		
Optimal display	using browser	
	80	
with resolution of 1	024 X 768 pixels	

User has to log into the system using registered User ID and its respective password. Click the [Login] button to proceed.

1.1 SIGN UP

Click on the ^{Sign Up} at the bottom of login form to display the following screen. Fill the following empty form and choose drop down list such as Business Registration No, Name, Username, Email,Password, Reconfirm Password and choose the radio button that has been highlighted to create new MDR-BCD account. After complete fill registration form user must verified email.

Business Registration No	ane system.	
Name		
Jsemame	Reason Create Account In Medcast	
Email	CAB Application	
Password	Notification Application	
Re-Confirm Password		

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

The user must verified email to completed the last step of the registration. Click on the link given to verified email in the system medcast V2.0.

MeDC@St Account Activation Index x	ē	
to me ●	*	*
Dear Sir/Madam		
Thank you for registering with MeDC@St, To complete the registration process, please click the following hyperlink to activate your account. The following are your account information:		
Business Registration Number : VT-5107 Name of Establishment : SYAK AMIRUL Email : <u>syakirinkirin12345@gmail.com</u> Login ID : VT-5107 Password : gwel12345		
If the above information are correct, please click here (link to MeDC@St Login Page) to activate your account.		
Copy the following line and paste into your web browser if you have problem with the activation link above: https://www.mda.gov.my/medcastv2/backend/web/index.php/admin/user/account-activation?key=3ef7fd5931365eb5936b0304811 5c3eb9939a	<u>ca7</u>	
Thank you MeDC@St Administrator		

The account activation screen will display. The user must click on the link to login into the account.

MEDCOSt v2.	MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM
Account Activation Succ	essful
USER SYAK AMIRUL	
Your Account Have Successfully Activated, Please Login To https://www.mda.gov.my/medcastv2/backend/web/index.php	The System At p/admin/user/login

The login screen will display.

MEDCOSt v2.	MEDICAL DEVICE CENTRALISE ONLINE APPLICATION SYSTEM
Username	Pengumuman
La Enter username	Test announcement sz (2017-10-21) Newl It lived approximate. Read More
Password	
Enter password	
Sign Up Reset Password FAQ Helpdesk Login	

ysia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)

The user login successfully in the system medcast. It shows the dashboard of the account.

MCDOS v2.0	Quick Search Q Allowand Search EXMANLE ()	ENGLISH o A (0) - STAKAMEREL - STAKAMEREL -
ĝi kont	Hans / Dathard	Catalitationand License Redical Concern Appendixon
 MEEKA BUNG HEASTMITCH X ACCOUT MANAGEMENT 	For An Logged in A Valo Account	Modale: Establishmert Liseree *
CELEREHELP		Charles and Carlos and
• Rates (1 @	CO199950000	Nut Vanapenset 🛛 👘 🖉
 Mirena desmark Disslerator Socialise stranets Socialise disserveds Socialise disserveds 	Shouling 1.2 of 2 tama.	No maulta bund.

2.0 NEW REGISTRATION

User click at [ESTABLISHMENT LICENSE] then click at [New Application Form] to go New Establishment Licensing Application page.



User tick at MANUFACTURER or AUTHORISED REPRESENTATIVE or DISTRIBUTOR or

IMPORTER checkbox and then click to go to the next step. If user tick 'MANUFACTURER' checkbox, then user cannot tick others application. If user tick

'MANUFACTURER' checkbox, then user cannot tick others application. If user tick 'AUTHORISED REPRESENTATIVE' checkbox, then user can tick others application except 'MANUFACTURER'.

Medical Device Registration Application
ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE
Next

2.1 ESTABLISHMENT DETAILS FORM

The diagram below show Establishment Licensing Form - 1.0 ESTABLISHMENT DETAILS.

All fields marked with * are mandatory		Application Details
Vienen al 🗙 na field investi fer beite		1.0 ESTABLISHMENT DETAIL
		2.0 PERSON RESPONSIBLE DETAILS
Establishment Detail		3.0 CONTACT PERSON DETAILS
1. Type Of Establishment : - * MANUFACT	URER	4.0 QUALITY MANAGEMENT DETAILS
		5.0 ATTESTATION FOR ESTABLISHMENT
2. Bumiputra Status * 🛈		Q PREVIEW & SUBMIT
VES ® NO		
Business Basistantian No.		
FRONTEND		
		_
4. Establishment Name 😡		
ZAED		
	Edablishment Usensing Application	
	Subject only can be done if all fields mandatory are camplete	
Kala Kalaka Kalaka Kalaka Kalaka Kalaka	Lifebilishneri Orial Chik S You Rom	The state of the s
a here ill'activitations	2.0 Person Responsible Details (1.5.3.1.) time mass	
uninations had k lye d fastions:- + second all	3.6 Cardiard Person Details (2.8 % in them them)	Ref.
Linguistics'#	4.0 Quality Management Initials Constants	
1 kees Aproximite Artif		
NUTE	"Submit only can be done if all fields mandatory, we complete	

1. Type of Establishment*

List of Type Of Establishment

Establishment Licensing Registration Form (SUBMISS	ION ID : EL-20171103-110)		Analiantian Datalla
All fields marked with * are mandatory			Application Details
Hover at Q on field input for help			2.0 PERSON RESPONSIBLE DETAILS
			3.0 CONTACT PERSON DETAILS
0 Establishment Detail			4.0 QUALITY MANAGEMENT DETAILS
1. Type Of Establishment : -	AUTHORISED REPRESENTATIVE		5.0 ATTESTATION FOR ESTABLISHM
			Q. PREVIEW & SUBMIT
<pre>i bit discussion: 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2</pre>	Lipload file * Supported Fil Uploaded Files :- TEST.pdf Menufacturer : EXAMPLE	e Type : pdf	

User click • Download Template For Letter Of Authorisation to download template for letter of authorisation.

User fills 'Name of Manufacturer' textbox. Next, user click to upload file. **The file must be pdf format and size not more than 300 MB**. Text that wrote in 'Name of Manufacturer' text box will display in 'Upload Files :-' section. **This step just for Authorised Representative application only.**

This step just for Distributor application only.



User click • Download Template For Distributor to

to download template for distributor.

📤 Upload file

User fills 'Name of Authorised Representative' text box. Next, user click to upload file. **The file must be pdf format and size not more than 300 MB**. Text that wrote in 'Name of Authorised Representative text box will display in 'Upload Files :-' section.**This step just for Distributor application only.**

12/62

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

This step just for Importer application only.



User click • Download Template For Importer to download template for importer.

User fills 'Name of Authorised Representative' text box. Next, user click to upload file. **The file must be pdf format and size not more than 300 MB**. Text that wrote in 'Name of Authorised Representative text box will display in 'Upload

Files :-' section.

Medical Device Authority, Ministry of Health Malaysia

ysia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)



a moved has not former and size not may then 700 MD

from MOF file. The file must be pdf format and size not more than 300 MB.

Establishment Licensing Registration For	rm (SUBMISSION ID : EL-20171103-109)		
All fields marked with * are mandatory		>	Application Details
			1.0 ESTABLISHMENT DETAIL
Hover at 🖗 on field input for help			2.0 PERSON RESPONSIBLE DETAILS
1.0 Establishment Detail			3.0 CONTACT PERSON DETAILS
1. Type Of Establishment : -	MANUFACTURER		4.0 QUALITY MANAGEMENT DETAILS
			5.0 ATTESTATION FOR ESTABLISHMENT
2. Bumiputra Status * NO YES NO YES NO Copy Of Bumiputra certificate from MOF * *	Maximum File Size : 300MB Supported File Type : PDF Only Uploaded Files :- TEST.pdf Name of pdf file will show he Click here to view file	ere.	Q PREVIEW& SUBMIT Click for downloadfile Click for remove file

If user tick 'NO' radio button, user can go to the next step.

3. Business Registration No*

System automatically fill this text box. User cannot edit that data in text box. System automatic fill the text box with data from registration process.

4. Establishment Name*

System automatically fill this text box. User cannot edit that data in text box. System automatically fill the text box with data from registration process.

3. Business Registration No 😡	
FRONTEND	Application Details
4. Establishment Name 🛛	1.0 ESTABLISHMENT DETAIL
ZAED	2.0 PERSON RESPONSIBLE DETAILS
	3.0 CONTACT PERSON DETAILS
5. Type Of Company * •	4.0 QUALITY MANAGEMENT DETAILS
Assumer File Size : 300MB Supported File Type : PDF Only	5.0 ATTESTATION FOR ESTABLISHMENT
Copy Of Business Registration / Document Establishment Name : ROC * Supported File Type : pdf	Q PREVIEW & SUBMIT
() († K) Park + Park = V () (anti-Fitter →)	
Ngenia + New Internation	
In Construction of the second	
This PC The P	ada Perniagaan

5. Type of Company*

That dropdown text box, if user select 'OTHER (LAIN-LAIN)' at Type Of Company text box, automatically text box 'Other (Please Specify)' will appear.

5. Type Of Company * OTHER (LAIN-LAIN)		>	Application Details
			1.0 ESTABLISHMENT DETAIL
Other (Please Specify) *		-1	2.0 PERSON RESPONSIBLE DETAILS
		-	3.0 CONTACT PERSON DETAILS
Copy Of Business Registration / Document Establishment Name : ROC	. Unload file * Supported File Type : odf		4.0 QUALITY MANAGEMENT DETAILS
Certificate O			5.0 ATTESTATION FOR ESTABLISHMENT
	Uploaded Files :-		Q PREVIEW & SUBMIT
	No Uploaded Files		

User Manual Front End User - Establishment License

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





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

2.2 PERSON RESPONSIBLE DETAILS

Nationality*

User choose to tick Malaysian or Non Malaysian . If user tick at 'Non Malaysia' radio button, user has to fill Working Permit textbox and click Upload file to upload Copy Of Working Permit file. The file must be pdf format and size not more than 300 MB.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171031-100)	
All fields marked with * are mandatory	Application Details
Hover at O on field input for help	1.0 ESTABLISHMENT DETAIL
	2.0 PERSON RESPONSIBLE DETAILS
2.0 Person Responsible Details	3.0 CONTACT PERSON DETAILS
Nationality * 🖸	4.0 QUALITY MANAGEMENT DETAILS
Malaysian 🛞 Non Malaysian	5.0 ATTESTATION FOR ESTABLISHMENT
Working Permit Copy Of Workin	Q PREVIEW & SUBMIT
Couldrie Der Der Der Der Der Der Der	CHRES
Fibrane Game	

If user tick 'Malaysian' check box, user has to fill NRIC/Passport No* text box and Upload Copy Of Person Responsible Identity Card (IC) file. **The file must be pdf format and size not more than 300 MB**.

2.0 Person Responsible Details	>	Application Details
Nationality * 🔾		1.0 ESTABLISHMENT DETAIL
Malaysian Non Malaysian		2.0 PERSON RESPONSIBLE DETAILS
		3.0 CONTACT PERSON DETAILS
NRIC/Passport No 1 U	_	4.0 QUALITY MANAGEMENT DETAILS
	_	5.0 ATTESTATION FOR ESTABLISHMENT
Copy Of Person Responsible's Identity Card (IC) 🕢 * Copy Of Person Responsible's Identity Card (IC) 🕡 *		Q PREVIEW & SUBMIT
Operator v New Midar New Midar New Midar Servit Account Convex Rat Prove Servit Prove 1952/14 (count) Convex Rat Prove Servit Prove		
In No. Uploaded Files		
Fits same All Fites Open Cancel		

Medical Device Centralised Online Application System (MeDC@St 2.0) User has to complete this field. For 'Date of Birth', user select date in calendar textbox or user can write the date using **YYYY-MM-DD** format.

Image:		_							
Su Ho Tu We Th Fr Sa 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 11 10 20 21 22 23 24 25 26 27 28 29 30 30 Application Details IName * O Sec Of Birth * O Sec Of Birth * O So Contact Person Responsible Details stignation From Top Management * O Sec Of Birth * O Sec Of Birth * O stignation From Top Management * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O Sec Of Birth * O		0	N	love	mber	20	17	0	
i i		Su	Mo	Tu	We	Th	Fr	Sa	
5 6 7 8 9 10 11 12 13 14 15 16 17 10 19 20 21 22 23 24 25 26 27 28 29 30 Application Details List of Birth * © Application Details List of Birth * © List of Birth * © </td <td></td> <td></td> <td></td> <td></td> <td>- 1</td> <td>2</td> <td>-3</td> <td>- 4</td> <td></td>					- 1	2	-3	- 4	
12 13 14 15 16 17 16 19 20 21 22 23 24 25 26 27 28 29 30 Application Details 10 ESTABLISHMENT DETAIL 1.0 ESTABLISHMENT DETAIL 2.0 PERSON RESPONSIBLE DETAILS a.0 Contract PERSON RESPOnsible DETAILS 3.0 Contract PERSON DETAILS 4.0 QUALITY MANAGEMENT DETAILS Select Designation From Top Management * O		5	6	7	8	9	10	11	
19 20 21 22 23 24 25 26 27 28 29 30 Application Details 1.0 ESTABLISHMENT DETAIL 1.0 ESTABLISHMENT DETAIL 2.0 PERSON RESPONSIBLE DETAIL 3.0 CONTACT PERSON DETAILS 4.0 QUALITY MANAGEMENT DETAIL 4.0 QUALITY MANAGEMENT DETAILS sep of Birth* 0		12	-13	14	15	16	17	18	
Name *		 -19	20	21	22	23	24	25	
Application Details 1.0 ESTABLISHMENT DETAIL 1.0 ESTABLISHMENT DETAIL 2.0 PERSON RESPONSIBLE DETAIL a.0 CONTACT PERSON DETAILS a.0 CONTACT PERSON DETAILS 4.0 QUALITY MANAGEMENT DETAIL se Of Birth* @ segnation From Top Management* @ SELECT DESIGNATION-	Name * O	20	21	20	29	30			
cc Of Birth * • 1.0 ESTABLISHMENT DETAIL 2.0 PERSON RESPONSIBLE DETAIL 2.0 PERSON RESPONSIBLE DETAILS a.0 CONTACT PERSON DETAILS 3.0 CONTACT PERSON DETAILS a.0 QUALITY MANAGEMENT DETAIL 4.0 QUALITY MANAGEMENT DETAILS signation From Top Management * • 5.0 ATTESTATION FOR ESTABLISH SELECT DESIGNATION- Q									Application Details
e Of Birth*	ce Of Birth * 🛛								1.0 ESTABLISHMENT DETAIL
e Of Birth*									2.0 PERSON RESPONSIBLE DETAI
COMBINATION- A.D. QUALITY MANAGEMENT DETA S.D. ATTESTATION FOR ESTABLISH Q. PREVIEW & SUBMIT									3.0 CONTACT PERSON DETAILS
ignation From Top Management * Q PREVIEW & SUBMIT SELECT DESIGNATION-	e Of Birth* 🧿								4.0 QUALITY MANAGEMENT DETA
Ignation From Top Management * Q FREVIEW & SUBMIT SELECT DESIGNATION-									5.0 ATTESTATION FOR ESTABLISH
SELECT DESIGNATION-	ignation From Top Management * 🛛								Q PREVIEW & SUBMIT
	SELECT DESIGNATION-								
	IRECTOR IANAGING DIRECTOR IANAGER SENERAL MANAGER IN DIRECTOR								
MANAGING DIRECTOR MANAGER GENERAL MANAGER	MD DIRECTOR CEO PRESIDENT VICE PRESIDENT								

If user select 'OTHER' at Designed From Top Management dropdown text box, automatically text box 'If Other, please specify' will appear.

tellerit 0		
run name ' V	- >	Application Details
	_	1.0 ESTABLISHMENT DETAIL
Place Of Birth * 🛛		2.0 PERSON RESPONSIBLE DETAIL
		3.0 CONTACT PERSON DETAILS
Date Of Birth*		4.0 QUALITY MANAGEMENT DETAIL
		5.0 ATTESTATION FOR ESTABLISH
Designation From Top Management * O		Q. PREVIEW & SUBMIT
OTHER		

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0) Next 🔶 User has to complete this field. User click to go to the next step or click 🔶 Previous to go to the previous form. KEDAH **KELANTAN** MELAKA NEGERI SEMBILAN PAHANG PERAK PERLIS PULAUT SABAH SARGINAR Correspondence Address * 😡 SELANCO TERENDGANU **Application Details** WILAYAH PERSEKUTUAN WILAYAH PERSEKUTUAN KUALA LUMPUR WILAYAH PERSEKUTUAN PUTRAJAYA 1.0 ESTABLISHMENT DETAIL 2.0 PERSON RESPONSIBLE DETAILS Postcode * 0 State * 🛛 City* 🛛 3.0 CONTACT PERSON DETAILS + SELANGOR AMPANG 4.0 QUALITY MANAGEMENT DETAILS 5.0 ATTESTATION FOR ESTABLISHMENT Fax* Telephone No * Q PREVIEW & SUBMIT *) 603 ٠ 603 Email* 🛛 6010 6011 6012 BANDAR PUNCAK ALAM 6013 BANTING BATANG BERJUNTAI 6014 Next 🔶 6015 6016 BATANG KALL BATU ARANG BATU CAVES BERANANG BUKIT ROTAN 6017 6019 CHERAS 604 605 **CYBERJAYA** DENGKIL HULU LANGAT

JENJAROM JERAM

KAJANG KAPAR

KERLING KLANG

606 607

6080

6081 6082 6083 Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

2.3 CONTACT PERSON DETAILS

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171031-100)	\$	Application Details				
All fields marked with * are mandatory		1.0 ESTABLISHMENT DETAIL				
Hower at 😡 on field input for help		2.0 PERSON RESPONSIBLE DETAILS				
		3.0 CONTACT PERSON DETAILS				
3.0 Contact Person Details		4.0 QUALITY MANAGEMENT DETAILS				
		5.0 ATTESTATION FOR ESTABLISHMENT				
● YES ● NO		Q PREVIEW & SUBMIT				
♦ Previous	Next 🌩					

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT*

User choose to click 🔍 YES or 🔍 NO .
If user tick at 'YES' radio button, user click \longrightarrow to go to the next form
or click to go to the previous form.



If user tick 'NO', then the user will be asked additional questions. User fill information about Nationality* of contact person.



must be pdf format and size not more than 300 MB.

3.0 Contact Person Details	
SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT * •	Application Details
VES IND	1.0 ESTABLISHMENT DETAIL
	2.0 PERSON RESPONSIBLE DETAILS
Nationality * 😡	3.0 CONTACT PERSON DETAILS
Malaysian Non Malaysian	4.0 QUALITY MANAGEMENT DETAILS
	5.0 ATTESTATION FOR ESTABLISHMENT
Working Permit @	Q PREVIEW & SUBMIT
Copy Of Working Permit Copy o	

NRIC/Passport No*

User enter NRIC/Passport No to the text box.

3.0 Contact Person Details	3.0 CONTACT PERSON DETAILS
	4.0 QUALITY MANAGEMENT DETAILS
SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT * •	5.0 ATTESTATION FOR ESTABLISHMENT
U YES U NO	Q PREVIEW & SUBMIT
Nationality * 🖸 🛞 Malaysian 🔘 Non Malaysian	
NRIC/Passport No * O	7

User has to complete this field. For 'Date of Birth' user select date in calendar textbox

or user can write the date using YYYY-MM-DD format. User click	🛓 Upload file	to
upload Designation : Letter of Authorization From Person Responsib	le file. The f	ile

must be pdf format and size not more than 300 MB.

		Ap	plica	ation	Deta	ils	
Ilara Of Ridh * 🖸		1.0 ESTA	BLISH	IMENT	DETAI	L	
and or on an a		2.0 PERS	SON RE	ESPON	ISIBLE	DETA	LS
		3.0 CON	TACT F	PERSO	N DET/	NLS	
ate Of Birth* 🖗		4.0 QUAI	ШТҮ М	IANAGE	EMENT	DETA	aL:
		5.0 ATTE	STATI	ON FO	R ESTA	BLISH	łM
esignation O			0.0			IDART	
esignation 😡			Q P	REVIE	wasu	/BMIT	
esignation 🖗 Designation : Letter of Authorization From Person Responsible 🚱 🍐 💶 🕹 Upload file 🔹 Supported File Type : pdf	0	No	Q P	nber	201	лвміт 7	
Designation : Letter of Authorization From Person Responsible	0 Su	No	Q P oven Tu	nber We	201 Th	ЈВМІТ 7 Fr 3	1
Designation : Letter of Authorization From Person Responsible Spen: Spen: State The RC + Reason Spen: State The RC + Reason Spen: Spen	0 Su 5	No Mo 6	Q P oven Tu 7	nber We	201 Th 2 9	7 7 Fr 3 10	5
Designation Designation : Letter of Authorization From Person Responsible Type: Type: Type: Type: Type: Type:	0 50 12	Nc Mo 6 13	Q P oven Tu 7 14	mber We 1 8	201 Th 2 9	7 7 Fr 3 10 17	5
Designation : Letter of Authorization From Person Responsible The second seco	0 Su 5 12 19	No Mo 6 13 20	Q P oven Tu 7 14 21	nber We 1 8 15 22	201 Th 2 9 16 23	7 Fr 3 10 17 24	5

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0) Next 🔶 User need to complete this field. User click to go to the next step or click 🔶 Previous to go to the previous form. **KELANTAN** MELAKA NEGERI SED PAHANG PERAK PERLIS Correspondence Address * 🔞 SABAH **Application Details** SARAMAK SELANGOR TERENGGANU WILKYAH PERSENUTUAN 1.0 ESTABLISHMENT DETAIL WILAYAH PERSENUTUAN KUALA LUMPUR MILAVAH PERSENUTUAN PUTRAJANA IN LABORN 2.0 PERSON RESPONSIBLE DETAILS City* 🛛 Postcode * 🛛 State * 🛛 3.0 CONTACT PERSON DETAILS SELECT STATE-. 4.0 QUALITY MANAGEMENT DETAILS Telephone No * 5.0 ATTESTATION FOR ESTABLISHMENT Fax* Q PREVIEW & SUBMIT 603 603 * Email * 🛛 6010 6011 BANDAR BARU BANGI 6012 Next 🔶 Previous BANDAR PUNCAK ALAM 6013 BANTING BATANG BERJUNTAI 6014 6015 BATANG KALI BATU ARANG 6016 BATU CAVES BERANANS BUNIT ROTAN 6017 6018 CHERAS CYBERJAYA 6019 DENGKOL 604 HULU LANGA 605 JENJAROM JERAM KAJANG 606 607 KAPAR KERLING KLANG 6080 6081 6082 6083

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

2.4 QUANTITY MANAGEMENT DETAILS

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171031-100)	
All fields marked with ⁺ are mandatory	Application Details
Hover at 🛈 on field input for help	1.0 ESTABLISHMENT DETAIL
	2.0 PERSON RESPONSIBLE DETAILS
4.0 Quality Management Details	3.0 CONTACT PERSON DETAILS
150 134852003	4.0 QUALITY MANAGEMENT DETAILS
Please Upload ISO 13485 Certificate and Audit Report	5.0 ATTESTATION FOR ESTABLISHMENT
	Q PREVIEW & SUBMIT
150 13485 Certificate 🛛 * Supported File Type : pdf	
Uploaded Files :-	
No Uploaded Files	
150 13465 Audit Report 🕼 Supported File Type : pdf	
→ → Φ K + TeisPC + Rebuses v (b) Search Potures (β)	
prise * Newfolder Res Grand Bitter Grand Bitter Company	
No Uploaded Files	
A Credite	
User B C This/PC Managament Advant Desirep Advant Managament	
Decoments Decoments Decoments	
3 Mak V ADD +	
Cancel	

ISO 13485 Certificate*

User click to upload ISO 13485 Certificate file. **The file must be pdf** format and size not more than 300 MB.

ISO 13485 Audit Report*

User click to upload ISO 13485 Audit Report file. The file must be

pdf format and size not more than 300 MB.

This step just for Authorised Representative, Distributor and Importer application only.

.0 Quality Management Details		
GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)		Application Details
Please upload certificate and Audit Report by CAB		1.0 ESTABLISHMENT DETAIL
		2.0 PERSON RESPONSIBLE DETAILS
GDPMD/ISO 13485 Certificate 😡 *	Lupload file * Supported File Type : pdf	3.0 CONTACT PERSON DETAILS
		4.0 QUALITY MANAGEMENT DETAILS
	Uploaded Files :-	5.0 ATTESTATION FOR ESTABLISHMEN
	No Uploaded Files	Q. PREVIEW & SUBMIT
GDPMD/ISO 13485 Audit Report 🖗 🍍	Lupload file * Supported File Type : pdf	
Copes X → → + + = + = + = + = + + + + + + + + +		
Organiza = Navafaldar = H = 3 @	Uploaded Files :-	
Displane location	No Uploaded Files	
A Dardine Contraction of the second s		

GDPMD/ISO 13485 Certificate*

User click

📤 Upload file

Open 💌 Canval

to upload GDPMD/ISO 13485 Certificate file. The file

must be pdf format and size not more than 300 MB.

GDPMD/ISO 13485 Audit Report*

User click to upload GDPMD/ISO 13485 Audit Report file. **The file**

must be pdf format and size not more than 300 MB.

Medical Device Authority, Ministry of Health Malaysia

vsia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)

User has to complete this field. User click



🔶 Previous

to go to the previous form.

	Name of CAB* 0	
	SELECT NAME OF CAR.	Application Details
	-Sector (Busic of Cub-	1.0 ESTABLISHMENT DETAIL
	Name Of Registered CAB Auditor * 🖸	2.0 PERSON RESPONSIBLE DETAILS
		3.0 CONTACT PERSON DETAILS
	CAB Registration No * O	4.0 QUALITY MANAGEMENT DETAILS
		5.0 ATTESTATION FOR ESTABLISHMENT
4	Certificate Expiry Date * 0	
	ARRAD	
	♦ Previous	
SITE TUV MED SOS SIRIE BSIS DQS TUV TUV CARE NQA BUR CLIN NQA BUR CLIN NQA BUR CLIN SIS SIS SIS SIS SIS SIS SIS SIS SIS S	ICT NAME OF CAR SUD IMALAYSIA SDN. BHD CERT MALAYSIA SDN. BHD (MALAYSIA) SDN. BHD MCAS INTERNATIONAL SDN. BHD SERVICES MALAYSIA SDN. BHD ICERTIFICATION (MI SDN. BHD REINLAND MALAYSIA SDN. BHD NORD (MI SDN. BHD ECENTIFICATION INTERNATIONAL (MI SDN. BHD ICERTIFICATION SUS SUS BHD. INDER SERVICES (MI SDN. BHD ITERNATIONAL CIRTIFICATION SDN. BHD INDE DIAMOND SDN. BHD. INDE DIAMOND SDN. BHD. INDE DIAMOND SDN. BHD. INDE DIAMOND SDN. BHD. INDE DIAMOND SDN. BHD.	

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

2.5 ATTESTATION FOR ESTABLISHMENT

3.0 Attentation For Establishment	
Medical Device Authority	Application Details
Date: 2017-12-04	1.0 ESTABLISHMENT DETAIL
Dear Si;	2.0 PERSON RESPONSIBLE DETAILS
Attestation For Establishment Licensing	3.0 CONTACT PERSON DETAILS
Person Responsible Name :	4.0 QUALITY MANAGEMENT DETAILS
DANISH AQNIA	S.D.ATTESTATION FOR ESTABLISHMENT
Person Responsible Identity Card Number :	Q PREVIEW & SUBMIT
970706385107	
The information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.	
Inderstand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.	
Previous Q PREVIEW & SUBMIT	J

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

The information provided correct and complete and co	f on this application and in any attached docume arrent to this date.	nts, certificates which had	been duly certified true copy	are accurate
I understand and acknow declaration, certificate or of	ledge that it is an offence under Section 76 of the her document which is untrue, inaccurate or misl	Medical Device Act 2012 (/ ieading,	Act 737) to make signs or furni	sh any
Previo		r		
Jser click	🔲 to go to the previous	; form. Click	Q PREVIEW & SUBMIT	to previev
pefore submitting	application			

before submitting application.

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



Submission only can do if all form status is Complete . If not, user need to complete

the form. Click

to submit application.

3.0 RENEWAL APPLICATION

User go to Application List page to renew application.



The diagram below show *Application List* page. Click ^{TRenewal} to renewal application.

=	Establishment Licensing - All Application						
FIL	FILTER APPLICATION						
No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL- 20171124- 83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	Q View C Renewal RAdvice & Receipt Ammendment Minor Ammendment Major Sumender
2	EL- 20171124- 85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	Q View PAdvice & Receipt

Medical Device Authority, Ministry of Health Malaysia

vsia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)

Next, user will go to 1.0 ESTABLISHMENT DETAILS page. User have to complete all

fields with (*). User click to go to the next step.

Establishment Licensing Registration Form (\$	SUBMISSION ID : EL-20171204-213)		
All fields marked with * are mandatory		۵	Application Details
Hower at 🖗 on field input for help			1.0 ESTABLISHMENT DETAIL
			2.0 PERSON RESPONSIBLE DETAILS
1.0 Establishment Detail			3.0 CONTACT PERSON DETAILS
1. Type Of Establishment : -	MANUFACTURER		4.0 QUALITY MANAGEMENT DETAILS
			5.0 ATTESTATION FOR ESTABLISHMENT
2. Bumiputra Status *			Q PREVIEW & SUBMIT
Copy Of Bumiputra certificate from MOF	Lipload file Supported File Type : pdf		
	Uploaded Files :-		
	TEST.pdf	▲ ×	

Hu

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. User have to complete all fields with (*).

Establishment Licensing Registration Form (SUE	3MISSION ID : EL-20171204-213)		
All fields marked with * are mandatory		-	Application Details
Hover at 9 on field input for help			1.0 ESTABLISHMENT DETAIL
			2.0 PERSON RESPONSIBLE DETAILS
Person Responsible Details			3.0 CONTACT PERSON DETAILS
Nationality*			4.0 QUALITY MANAGEMENT DETAILS
 Malaysian Non Malaysian 			5.0 ATTESTATION FOR ESTABLISHME
NRIC/Passport No *			Q PREVIEW & SUBMIT
970706385107			
Copy Of Person Responsible's Identity Card (IC) *	Lupload file Supported File Type : pdf		
	Uploaded Files :-		
	TEST.pdf	▲ ×	

User click	to go to the next step. User click	← Previous	to go to the
previous form.			

Medical Device Authority, Ministry of Health Malaysia

vsia User Manual Front End User - Establishment License Medical Device Centralised Online Application System (MeDC@St 2.0)

The diagram below shows 3.0 CONTACT PERSON DETAILS form. User have to fill all fields with (*).

All Robbs marched with ⁴ are marcheders.		Application Details
All helds marked with are mandatory		Application Details
Hover at 😡 on field input for help	14	ESTABLISHMENT DETAIL
	2/	PERSON RESPONSIBLE DETAILS
Contact Person Details	3.	CONTACT PERSON DETAILS
SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *	4.1	QUALITY MANAGEMENT DETAILS
○ YES ● NO	5.	ATTESTATION FOR ESTABLISHM
		Q PREVIEW & SUBMIT
Nationality*		
Malaysian Non Malaysian		
NRIC/Passport No *		
970706385107		

User click	to go to the next step. User click	🔶 Previous	to go to the
previous form.			

Medical Device Centralised Online Application System (MeDC@St 2.0) The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. User have to complete all fields with (*). In this form, the user has to upload ISO 13485 Certificatej and ISO 13485 Audit Report (for manufacture application).

All fields marked with " are mandatory		Application Details
Hover at 🕑 on field input for help		1.0 ESTABLISHMENT DETAIL
		2.0 PERSON RESPONSIBLE DETAILS
1.0 Quality Management Details		3.0 CONTACT PERSON DETAILS
150 13485:2003		4.0 QUALITY MANAGEMENT DETAILS
Please Upload ISO 13485 Certificate and Audit Report		5.0 ATTESTATION FOR ESTABLISHMENT
		Q. PREVIEW & SUBMIT
ISO 13485 Certificate 😡	Luplood file * Supported File Type : pdf	
	Uploaded Files :-	
	No Uploaded Files	
ISO 13465 Audit Report 😡		
	Upload No Supported File Type : pdf	
↑ No.PC > Patient w ⊗ Insult Patient	2	
A Caresa Rat Picasa Sand Pictures Sciences	Uploader Files :-	
and below the second seco	No Uploaded Files	
np Admin Middale		
	~	
File name.		
Open 💌 Care	<i>a</i>	
Lupload file	be file must be add formed	t and cize not mar
	ne me must be pui forma	L and Size not more
Next 🍝		🔶 Previous

n

Ö

GDPMD/ISO 13485 Certificate and GDPMD/ISO 13485 Audit Report (for Authorised Representative, Distributor and Importer application).

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)		Application Details
Please upload certificate and Audit Report by CAB		
		1.0 ESTABLISHMENT DETAIL
GDPMD/ISO 13485 Certificate @		2.0 PERSON RESPONSIBLE DETAILS
	Upload file Supported File Type : pdf	3.0 CONTACT PERSON DETAILS
		4.0 QUALITY MANAGEMENT DETAILS
	Uploaded Files :-	5.0 ATTESTATION FOR ESTABLISHMENT
	No Uploaded Files	Q. PREVIEW & SUBMIT
GDPMD/ISO 13485 Audit Report D	Lupload file * Supported File Type : pdf	
Open Open	Uploader Files :- No Uploaded Files	
ck Lypload file to upload. The	e file must be pdf forma	t and size not more
0 MB . User click	to go to the next step. Use	r click en and to
o provious form		



🔶 Previous

to go to the previous form.

Name of CAB * 😧			Application Details
-SELECT NAME OF CAB-			Application Details
			1.0 ESTABLISHMENT DETAIL
Name Of Registered CAB Auditor * 😡			2.0 PERSON RESPONSIBLE DETAILS
			3.0 CONTACT PERSON DETAILS
CAB Registration No * 0			4.0 QUALITY MANAGEMENT DETAILS
			5.0 ATTESTATION FOR ESTABLISHM
Certificate Expiry Date * 🛛			Q PREVIEW & SUBMIT
ajota	0		
🔶 Previous		Next	•
ICT NAME OF CAR.			
UD (MALAYSIA) SDN. BHD			
ERT MALAVSIA SDN. BHD. MALAVSIA SDN. BHD.			
GAS INTERNATIONAL SDN. BHD.			
ERVICES MALAYSIA SDN, BHD			
CERTIFICATION (M) SDN. BHD			
KORD (MI SON, BHD			
CERTIFICATION INTERNATIONAL (M) SDN. BHD			
CERTIFICATION SERVICES (M) SDN. BHD.			
TAU VERITAS CERTIFICATION (M) SDN. BHD			
CERTIFICATION SDN, BHD			
NORSKE VERITAS SDN. BHD			
INUM SHAUFFMANTZ VERITAS SDN. BHD.			
UINE DIAMOND SDN. BHD.			
BRAT CAB 2			
NINI UND B			

The diagram below show 5.0 form. User have to fill all fields with (*).

Attestation For Establishment	
Medical Device Authority	Application Details
Date: 2017-12-04	1.0 ESTABLISHMENT DETAIL
Dear Sir,	2.0 PERSON RESPONSIBLE DETAILS
Attestation For Establishment Licensing	3.0 CONTACT PERSON DETAILS
Person Responsible Name :	4.0 QUALITY MANAGEMENT DETAILS
DANISH AQWA	5.0 ATTESTATION FOR ESTABLISHMENT
Person Responsible Identity Card Number :	Q, PREVIEW & SUBMIT
970706385107	
The information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.	
Understand and advnowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.	
Previous Q, PREVIEW & SUBMIT	

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

The information provided on correct and complete and current	this application and in any attached documents, certificates which ha it to this date.	ad been duly certified true copy	are accurate
I understand and acknowledg declaration, certificate or other of	e that it is an offence under Section 76 of the Medical Device Act 2012 Jocument which is untrue, inaccurate or misleading.	(Act 737) to make signs or furni	sh any
User click	to go to the previous form. Click	Q PREVIEW & SUBMIT	to preview
before submitting ap	plication.		·

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



Submission only can do if all form status is Complete . If not, user need to complete

the form. Click

to submit application.

4.0 AMENDMENT MINOR

User go to Application List page yo renew application.



The diagram below show Application List page. Click • Ammendment Minor to make amendment minor.

=	Establishment Licensing - All Application									
FILT	FILTER APPLICATION Showing 1-2 of 2 items.									
No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action			
1	EL- 20171124- 83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	Q View S Renewal RAdvice & Receipt Ammendment Minor Ammendment Major Murender			
2	EL- 20171124- 85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	Q View PAdvice & Receipt			

Next, user will go to 1.0 ESTABLISHMENT DETAILS page. In this form user make changes at :

- I. 2. Bumiputra Status
- II. 7. State hi u
- III. 8. City
- IV. 9. Postcode
- V. 10. Telephone No
- VI. 11. Fax
- VII. 12. Company Website

Establishment Licensing Registration Form (SUB			
All fields marked with * are mandatory		>	Application Details
Howard 🖨 on field insut for bala			1.0 ESTABLISHMENT DETAIL
ноченах от пена праста: пер			2.0 PERSON RESPONSIBLE DETAILS
1.0 Establishment Detall			3.0 CONTACT PERSON DETAILS
1. Type Of Establishment : -	MANUFACTURER		4.0 QUALITY MANAGEMENT DETAILS
			5.0 ATTESTATION FOR ESTABLISHMENT
2. Bumiputra Status*			Q PREVIEW & SUBMIT
🖲 YES 🔍 NO			
Copy Of Bumiputra certificate from NOF *	Lupload file Supported File Type : pdf		
	Uploaded Files :-		
	No Uploaded Files		

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. In this form user make changes at :

I. Date of Birth

Establishment Licensing Registration Form (SUBMIS	SSION ID : EL-20171205-95)		
All fields marked with * are mandatory		•	Application Details
Hower at 😡 on field insut for help		1.0 E	STABLISHMENT DETAIL
		2.0 P	ERSON RESPONSIBLE DETAILS
2.0 Person Responsible Details		3.0 0	ONTACT PERSON DETAILS
Nationality *		4.0 Q	UALITY MANAGEMENT DETAILS
Malaysian Non Malaysian		5.0 Å	TTESTATION FOR ESTABLISHMENT
NBIC/Passport No *			Q PREVIEW & SUBMIT
111111111111			
Copy Of Person Responsible's Identity Card (IC) *	Uploaded Files :- TEST.pdf	≜ ×	

Medical Device Centralised Online Application System (MeDC@St 2.0) The diagram below shows 3.0 CONTACT PERSON DETAILS form. In this form, if user tick NO at SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT field, user to fill :

- I. Nationality (if user tick *Non Malaysian*, user has to upload Working Permit)
- II. Working Permit
- III. NRIC/Passport No
- IV. Full Name
- V. Place Of Birth
- VI. Date Of Birth
- VII. Designation (Designation : Letter of Authorization From Person Responsible)
- VIII. Correspondence Address
 - IX. Postcode
 - X. State
 - XI. City
- XII. Telephone No
- XIII. Fax
- XIV. Email

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)		
All fields marked with [*] are mandatory	•	Application Details
Hover at O on field input for help	1.0	ESTABLISHMENT DETAIL
	2.0	PERSON RESPONSIBLE DETAILS
3.0 Contact Person Details	3.0	CONTACT PERSON DETAILS
SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *	4.0	QUALITY MANAGEMENT DETAILS
VES 🖲 NO	5.0	ATTESTATION FOR ESTABLISHMENT
		Q PREVIEW & SUBMIT
Nationality *		
Malaysian Non Malaysian		
Working Permit		
Copy Of Working Permit Lupload file * Supported File Type : pdf		

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

The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. In this form user make changes at :

- I. ISO 13485 Certificate/GDPMD/ISO 13485 Certificate.
- II. ISO 13485 Audit Report/GDPMD/ISO 13485 Audit Report
- III. Name of C.A.B

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)							
All fields marked with * are mandatory		>	Application Details				
Hover at \varTheta on field input for help			1.0 ESTABLISHMENT DETAIL				
			2.0 PERSON RESPONSIBLE DETAILS				
4.0 Quality Management Details			3.0 CONTACT PERSON DETAILS				
ISO 13485:2003			4.0 QUALITY MANAGEMENT DETAILS				
Please Upload ISO 13485 Certificate and Audit Report			5.0 ATTESTATION FOR ESTABLISHMENT				
			Q. PREVIEW & SUBMIT				
ISO 13485 Certificate	Lupload file * Supported File Type : pdf						
	Uploaded Files :-						
	TEST.pdf	* *					
ISO 13485 Audit Report *	Lupload file * Supported File Type : pdf						

The diagram below show 5.0 ATTESTATION FOR ESTABLISHMENT form.

5.0 Attestation For Establishment	
Medical Device Authority	Application Details
Date: 2017-12-04	1.0 ESTABLISHMENT DETAIL
Dear Sir,	2.0 PERSON RESPONSIBLE DETAILS
Attestation For Establishment Licensing	3.0 CONTACT PERSON DETAILS
Person Responsible Name :	4.0 QUALITY MANAGEMENT DETAILS
DARISH AQINA	5.0 ATTESTATION FOR ESTABLISHMENT
Person Responsible Identity Card Number :	Q PREVIEW & SUBMIT
970706395107	
The information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.	
In understand and advowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.	
Previous Q PREVIEW & SUBMIT	

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

The information provided on the correct and complete and current	his application and in any attached documents, certificates which hi to this date.	ad been duly certified true copy	are accurate
I understand and acknowledge declaration, certificate or other de	that it is an offence under Section 76 of the Medical Device Act 2012 ocument which is untrue, inaccurate or misleading.	t (Act 737) to make signs or furni	sh any
User click	to go to the previous form. Click	Q PREVIEW & SUBMIT	to preview
before submitting app	blication.		to preview

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



Submission only can do if all form status is Complete . If not, user need to complete

the form. Click

to submit application.

5.0 AMENDMENT MAJOR

User go to Application List page yo renew application.



The diagram below show Application List page. Click +Ammendment Major to make amendment major.

=	Establishment Licensing - All Application								
FILT	FILTER APPLICATION Showing 1-2 of 2 items.								
No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action		
1	EL- 20171124- 83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	Q View S Renewal RAdvice & Receipt O Anmendment Minor Ammendment Major Museum		
2	EL- 20171124- 85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	Q View PAdvice & Receipt		

User Manual Front End User - Establishment License

Medical Device Centralised Online Application System (MeDC@St 2.0) Next, user will go to 1.0 ESTABLISHMENT DETAILS page. In this form user make changes at :

- I. 2. Bumiputra Status
- II. 4. Establishment Name
- III. 5. Type Of Company
- IV. 6. Address

Establishment Licensing Registration Form (SUBMISSIO	N ID : EL-20171207-100)		
All fields marked with * are mandatory		N	Application Details
House at O on field innut for belo			1.0 ESTABLISHMENT DETAIL
			2.0 PERSON RESPONSIBLE DETAILS
1.0 Establishment Detail			3.0 CONTACT PERSON DETAILS
1. Type Of Establishment : -	AUTHORISED REPRESENTATIVE		4.0 QUALITY MANAGEMENT DETAILS
	IMPORTER		5.0 ATTESTATION FOR ESTABLISHMENT
			Q. PREVIEW & SUBMIT
AUTHORISED REPRESENTATIVE O	Uploaded Files :-		
Download Template For Letter Of Authorisation	TEST.pdf File Remark I AR X	▲ ×	
	MDR A UAT PAT FAT.pdf	▲ ×	
IMPORTER 😡 🄺	Uploaded Files :-		
The following supporting document is required :	TEST.pdf	≜ ×	
1. Authorization Letter from Authorised Representative	MDR A UAT PAT FAT.pdf	≜ ×	

Medical Device Authority, Ministry of Health Malaysia

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. In this form user can make changes at all field.

Establishment Licensing Registration Form (SUBMIS	ISION ID : EL-20171207-100)		
All fields marked with [*] are mandatory		>	Application Details
Hower at O on field input for help			1.0 ESTABLISHMENT DETAIL
			2.0 PERSON RESPONSIBLE DETAILS
2.0 Person Responsible Details			3.0 CONTACT PERSON DETAILS
Nationality*			4.0 QUALITY MANAGEMENT DETAILS
Malaysian Non Malaysian			5.0 ATTESTATION FOR ESTABLISHMENT
New Certificate And Audit Report Need To Be Uploaded For Ammend	ment Major		Q PREVIEW & SUBMIT
Working Permit			
123456			
Copy Of Working Permit	2 Upload file Supported File Type : pdf		
	Uploaded Files		
	Uploaded Files :- TEST odf		

Medical Device Centralised Online Application System (MeDC@St 2.0) The diagram below shows 3.0 CONTACT PERSON DETAILS form. In this form, if user tick NO on *SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT* field, user need to complete all fields.

Establishment Licensing Registration Form (SUBMISSION ID	: EL-20171205-95)		
All fields marked with * are mandatory		» <i>i</i>	opplication Details
Hover at O on field input for help		1.0 EST	ABLISHMENT DETAIL
		2.0 PE	RSON RESPONSIBLE DETAILS
3.0 Contact Person Details		3.0 CD	NTACT PERSON DETAILS
SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *		4.0 QU	ALITY MANAGEMENT DETAILS
VES 🖲 NO		5.0 AT1	ESTATION FOR ESTABLISHMENT
			Q PREVIEW & SUBMIT
Nationality *			
🔍 Malaysian 🖲 Non Malaysian			
Working Permit		_	
Copy Of Working Permit	L Upload file * Supported File Type : pdf		

Medical Device Centralised Online Application System (MeDC@St 2.0) The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. In this form user make changes at :

I. Name of CAB

Name of CAB* 0	Application Details
CABUSER	
	1.0 ESTABLISHMENT DETAIL
Name Of Registered CAB Auditor *	2.0 PERSON RESPONSIBLE DETAILS
AHNAD FADHILLAH	3.0 CONTACT PERSON DETAILS
CAB Registration No* 😡	4.0 QUALITY MANAGEMENT DETAILS
CABUSER	5.0 ATTESTATION FOR ESTABLISHMENT
Certificate Expiry Date*	Q PREVIEW & SUBMIT
2020-11-21	

The diagram below show 5.0 ATTESTATION FOR ESTABLISHMENT form.

5.D Attestation For Establishment	
Medical Device Authority	Application Details
Date: 2017-12-04	1.0 ESTABLISHMENT DETAIL
Dear Sir,	2.0 PERSON RESPONSIBLE DETAILS
Attestation For Establishment Licensing	3.0 CONTACT PERSON DETAILS
Person Responsible Name :	4.0 QUALITY MANAGEMENT DETAILS
DANISH AQIVA	5.0 ATTESTATION FOR ESTABLISHMENT
Person Responsible Identity Card Number :	Q PREVIEW & SUBMIT
970706385107	
The information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.	
iii Lunderstand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.	
Previous Q PREVIEW & SUBMIT	

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

The information provided on the correct and complete and current	his application and in any attached documents, certificates which hi to this date.	ad been duly certified true copy	are accurate
I understand and acknowledge declaration, certificate or other de	that it is an offence under Section 76 of the Medical Device Act 2012 ocument which is untrue, inaccurate or misleading.	t (Act 737) to make signs or furni	sh any
User click	to go to the previous form. Click	Q PREVIEW & SUBMIT	to preview
before submitting app	blication.		to preview

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



Submission only can do if all form status is Complete . If not, user need to complete

the form. Click

to submit application.

6.0 WITHDRAWAL

User go to Application List page yo renew application.



The diagram below show Application List page. Click ******Withdrawal* to withdrawal application.

=	Establishme	nt Licensing	- All Application				
FIU	ER APPLICATION	N.					
Showi	ng 1-3 of 3 item	5.					
No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL- 20171124- 83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	Q View PAdvice & Receipt
2	EL- 20171124- 85	2017-11-24 03:07:00	NEW REGISTRATION	COMPLETE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	Q View 13 Renewal PAdvice & Receipt Q Anvenendment Minor + Ammendment Major > Surrender
3	EL- 20171204- 213	2017-12-04 18:08:35	RENEWAL	EVALUATION	MANUFACTURER	ACTIVE	Q View PAdvice & Receipt X Withdrawal

The diagram below show Establishment Licensing-SURRENDER APPLICATION form.

RENDER APPLICATION - EL-201711	24-85	
Name Of Establishment	: DANISH AQWA	
Business Registration No	: EL_TEST	
License No	: MDA-0032-WDP10117	
Type Of License	AUTHORISED REPRESENTATIVE Distributor Importer	
Expire Date Of License	: 2020-11-27	
Applicant	-Select Applicant-	•
Document Of Surrender	Reason Of Surrender	
No results found.	4	» //
	Submit To Surrender	- 1
		•

file must be pdf format and size not more than 300 MB), and Reason Of

Surrender field. Next, click

Submit To Surrender to submit.

57/62

7.0 SURRENDER

User go to Application List page to renew application.



The diagram below show Application List page. Click Surrender to surrender an application.

=	Establishme	nt Licensing	- All Application				
FU	ER APPLICATION	N					
Showi	ng 1-3 of 3 item	s.					
No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL- 20171124- 83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	Q View
2	EL- 20171124- 85	2017-11-24 03:07:00	NEW REGISTRATION	COMPLETE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	Q View C3 Renewal PAdvice & Receipt Ammendment Minor Ammendment Major Surrender
з	EL- 20171204- 213	2017-12-04 18:08:35	RENEWAL	EVALUATION	MANUFACTURER	ACTIVE	Q View PAdvice & Receipt N Withdrawal

The diagram below show Establishment Licensing-SURRENDER APPLICATION form.

Name Of Establishment	: DANISH AQWA	
Business Registration No	: EL_TEST	
License No	: MDA-0032-WDP10117	
Type Of License	AUTHORISED REPRESENTATIVE	
	Distributor	
	Importer	
Expire Date Of License	: 2020-11-27	
lpplicant	-Select Applicant-	•
Document Of Surrender	Reason Of Surrender	
± Upload file		
No results found.		
	4	× //
	neuronal and a second second	

file must be pdf format and size not more than 300 MB), and Reason Of

Surrender field. Next, click

Submit To Surrender to submit.

8.0 CHANGE OF OWNERSHIP

Click on the 'ESTABLISHMENT LICENSE" at the left menu sidebar and click on the 'Change Of Ownership' to create a new form.



The diagram below show Change of Ownership page.

Establishme	ent License - Change Of Owners	hip	
REGISTRATIO	N NO :		
*Please Insert *Please Ensur Search Applic	: Full REGISTRATION NO : Example : GA7 'e New Authorised Representative or Ne ration	639017-1 w Manufacturer submit the Change Ownership Registration	
No	License No	Establishment Name	Action

Search Application

to search the

User fill the '*REGISTRATION NO*' text boxes and click registration number. The registration number must be from other establishment user.

	REGISTR	ATION NO :			
	*Please *Please Search	Insert Full REGISTRATION NO : Ex Ensure New Authorised Represen	mple : GA7639017-1 zable or New Manufacturer submit the Change Ow	tership Registration	
	No	License No	Establishment Name	Action	
	1	GC6674719-28942	SI SDN BHD	Q, View Q, Change Of Ownership	
MDR-20190516- *Click On The Tale To View Desals Section 1 : Medical Device Classification 1.0 Risk Type Classification			Campia Campia	Change of Owner (In accordance with Groudar Ester of Change Of Ownership Application is applicable for)	Annex A ship For Medical Device Registration Application Form of Ownership for Medical Device Registration Application form dedical Device Austhority No. 3 Year 2018 : Change of Ownership for Medical Device Registration)
1.1 Establishment Details					
1.1 Establishment Details				 Authorised Representative Local Manufacturer who intend to transfer the ownership of the device to another to	her Authorised Representative / Local Manufacturer
1.1 Establishment Details Section 2 : General Information				1. Authorised Representative 2. Local Manufacturer who intend to transfer the ownership of the device to ano NEW	her Authorised Representative / Local Manufacturer AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER
1.1 Establishment Details Section 2 : General Information				1. Authorised Representative 2. Local Manufacture who intend to transfer the ownership of the device to ano NEW Name of Establishment :	her Authorised Representative / Local Manufacturer AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER
1.1 Establishment Details Section 2 : General Information 2.0 General Information			Complete	Authorised Representative Local Manufacture who intend to transfer the ownership of the device to ano New New Name of Establishment : Address : Case SERDANC	her Authorised Representative / Local Manufacturer AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER
1.1 Establishment Details Section 2 : General Information 2.0 General Information			Complete	C. Authorized Representative Leader and a second	her Authorised Representative / Local Manufacturer AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER Soute : SELANGOR
1.1 Establishment Details Section 2 : General Information 2.0 General Information Section 3 : Medical Device Grouping			Constant	Authorized Representative Lead Manufacture who intend to transfer the ownership of the device to and NOW None of Establishmene : Address : Cry SERDANG Establishment License Number : MDA:0001: None of Consta Person :	her Authorised Representative / Local Manufacturer AUTHORIZED REPESTINTATIVE / NEW LOCAL MANUFACTURER Sone : SELANGOR Designation : MARAGER
1.1 Establishmen: Details Section 2: General Information 2.0 General Information Section 3: Medical Device Grouping			Campion	Authorized Representative Lead Mundicuture who intends to transfer the ownership of the device to and NEW Nome of Stablishment: Address: Coy: SERONG Establishment:Leans Number : MDA-0001: Name of Contact Person: Telephone No:	her Authorised Representative / Local Manufecturer AUTHORIZID REPRESENTATIVE / NEW LOCAL MANUFACTURER Sonte : SELANGOR Designation : MANAGER Mobile Phone No : nal Address :
1.1 Establishmen: Details 2.0 General Information 2.0 General Information Section 3: Medical Device Grouping 1.0 Medical Device Grouping			Complet	Automatic Representation Automatic Representation Automatic Representation Neurol of Establishment L Coy SERDANG Establishment Literare Number / MDA-6001- Neuro of Contact Person 1 Telephone No1 CURRENT	her Authorised Representative / Local Manufacturer AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER Sone : SELANGOR Degration : MANAGER Mobile Phone No : nal Address : AUTHORIZED REPRESENTATIVE / CURRENT LOCAL MANUFACTURER
1.1 Establishmen: Details Section 2: General Information 2.0 General Information Section 3: Medical Device Grouping 3.0 Medical Device Grouping			Complex	Authorized Representative Lead Manufacture who initial to sound's the conversible of the device to ane who initial to sound's the conversible of the device to ane Norme of Stabilishment : Cry SERDING Establishment License Number : MDA-0001-' Name of Charact Person 1 Telephone No : CURRINT Name of Establishment	her Authorhed Representative / Local Manufacturer AUTHORZED REPESINTATIVE / NUN LOCAL MANUFACTURER Some: SELANGOR Designation: MANAGER Mobile Phone No: nul Address: AUTHORZED REPESINTATIVE / CURRENT LOCAL MANUFACTURER
1.1 Establishmen: Details Section 2 - General Information 2.0 General Information Section 3 - Medical Device Grouping 3.0 Medical Device Grouping Fording 4 - GPD			(complete)	Authorized Representative Lead Manufacture who intend to transfer the ownership of the device to ann New None of Exablationers: City: SERONG Exablationer: City: SERONG Sablationer: CURRENT Name of Exablationer: Address: CURRENT	her Authorised Representative / Local Manufacturer AUTHORIZID REPRESENTATIVE / NUN LOCAL MANUFACTURER Sonte: SELANGOR Designation: IMANAGER Mobile Phone No : nal Address : AUTHORIZID REPRESENTATIVE / CURRENT LOCAL MANUFACTURER
1.1 Establishmen: Denails Section 2 : General Information 2.0 General Information Section 3 : Medical Device Grouping 3.0 Medical Device Grouping Section 4 : CLOT			Complex	Automical Representation Automical Representation Automical Representation Neuro of Establishment I: Representation	her Authorised Representative / Local Manufecturer AUTHORIZID REPRESENTATIVE / NEW LOCAL MANUFACTURER Sone: SELANGOR Designation: MANAGER Mobile Phone No: nal Address : AUTHORIZED REPRESENTATIVE / CURRENT LOCAL MANUFACTURER Sone: SELANGOR Sone: SELANGOR Sone: SELANGOR

- Click **Qview** to view the application.
- Click Change Of Ownership to proceed the process change of ownership



Uploaded F	Files:-	
No resu	ults found.	
		nreign Manufacturar)
Fermination + Select fil Uploaded F No resu	ie Supported File Type : pdf Files:- Jlts found.	
Fermination + Select fil Uploaded F No resu	ILetter (Current Authorised Representative Terminated by The ie	ETAILS OF MEDICAL DEVICES
Fermination Select fil Uploaded F No resu No	Iterter (Current Authorised Representative Terminated by The ie Supported File Type : pdf Files:- Jits found. MEDICAL DEVICE NAME	ETAILS OF MEDICAL DEVICES

After the change of ownership is submit the application will be in evaluation stage. After approval stage, applicant is required to pay for registration fee to proceed with the change of ownership. Below show the flow before change of ownership is complete.

