# USER MANUAL FRONT END USER

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

**MODUL UTAMA - MDR CLASS B, C & D** 

**DISEDIAKAN OLEH :** 



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#### **1.0 INTRODUCTION**

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://www.mda.gov.my/medcastv2/backend/web/index.php/admin/user/logivb n

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

Username	Pengumuman	
L Enter usemame	Testing public (primica) Newl Sense of Trial or e. Read More.	
Password	Test announcement st (2017-10-21) New! It lived approximate. Read More.	
Enter password		
Sign Up   Reset Password   FAQ   Helpdesk	gn	

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

#### 1.2 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, E-mail, Address, State, City, Postcode, Telephone No, Fax No, 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	no de system.
Name	
Usemame	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 at the link given to verified email in the system medcast V2.0.



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

Medcost,	<b>2.0</b> MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM
Account Activation Suc	cessful
USER SYAK AMIRUL	
Your Account Have Successfully Activated, Please Logi https://www.mda.gov.my/medcastv2/backend/web/inde	in To The System At x.php/admin/user/login

The login screen will display.

VEDCOSt v2.0	MEDICAL DEVICE CENTRALISE ONLINE APPLICATION SYSTEM
Username	Pengumuman
💄 Enter username	Test announcement sz (2017-10-21) Newl It lived approximateRead More
Password	
Enter password	
Sign Up   Reset Password   FAQ   Helpdesk Login	

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

VEDCOS v2.0	(Juid-Sarch) Damy ( @	🕿 Emilion 🔹 🛔 🕅 -	STAKAHERL-STAKAHERL -
₫ HOME - •	Hone / Dathord		Eduktorisent Coarse Medical Device Reptration
<ul> <li>MEERSAL EEVACE RECENTRATION</li> <li>X ACCOUNT MARAGEMENT</li> </ul>	Fan An Laggel in As Vais Account	Habin	Establishment Listman •
Objekte HELP      Objekte		0 Referen Filler	Declayable of the second secon
* Mary(1)@	teromonist 00	Alert Wasagement	See 1
Indreese documents     Crouter inter     Outdate inter     Outdates documents     Outdates documents	Stewing 1-2 of 2 hans. • Instructions from • optimizer (c) (c) • instructions (c) (c) • instructio	No manifa from d.	

#### 2.0 NEW REGISTRATION

# \*\*User must create new Establishment License first to create new Medical Device Registration (Refer User Manual EL Front End User)

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'New Application Form' to create a new form.



application and click on the button

Tick on the 'MANUFACTURER' or 'AUTHORISED REPRESENTATIVE' to create new



to proceed. User can make one application at one

time. 'Next' button will enable after user tick applications checkbox.



After click

Next

the diagram will show.

Medical Device Registration Application	
ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE	
MANUFACTURER	
** SELECTING CLASS OF MEDICAL DEVICE WILL AUTOMATICALLY REDIRECT USER TO APPLICATION FORM WITHOUT HAVING TO DO RISK CLASSIFICATION ** DEFAULT SELECTION WILL REDIRECT TO RISK CLASSIFICATION	
 CLASS OF MEDICAL DEVICE	
-GO TO RISK CLASSIFICATION FORM-	٠

In class of medical device section you can choose CLASS A, CLASS B, CLASS C and CLASS D but also you can choose GO TO RISK CLASSIFICATION FORM.

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Module Utama MDR Class B,C & D Medical Device Centralised Online Application System (MeDC@St 2.0)

CD	ASS OF MEDICAL DEVICE
	-GO TO RISK CLASSIFICATION FORM-
	-GO TO RISK CLASSIFICATION FORM-
(	CLASS A
(	CLASS B
0	CLASS C
(	CLASS D
_	

If the user choose GO TO RISK CLASSIFICATION FORM and click section will be display.

the classification

Next

E Classification	
Device Condition	
NEW      REFURBISHED      USED	
Device Type	
GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE	
General Medical Device (GMD) Type	
NON-INVASIVE DEVICE      INVASIVE DEVICE      ACTIVE DEVICE      ADDITIONAL RULES	
NON-INVASIVE DEVICE RULES	
RULE1 ORULE2 ORULE3 ORULE4	
RULE 1 Details	
Medical device that is intended to be in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate	

If the user choose CLASS A and click

Next

the Class A Application will be display.

Class A Application (MDR-201808	10-13)		$\sim$		
Medical Device Risk And Classification Details					
** RISK RULE DETAIL LIST WILL APPEAR ONLY IF MEDICAL DEVICE CLASS AND MEDICAL DEVICE RISK TYPE HAVE BEEN SELECTED					
Medical Device Class	1	Class A			
Medical Device Type	1	-SELECT-	*		
Medical Device Risk Type	1	-SELECT-	٠		
Medical Device Rule Detail					
** PLEASE MAKE CHANGES ON RULE DETA	IL, MEDICAL DE	VICE INTENDED USES WILL REFRESH AFTER RULE DETAIL HAVE BEEN CHANGES			
Medical Device Rule	1				
1. Rule Can Only Be Changed By Alteri	1. Rule Can Only Be Changed By Altering Risk Rule Detail				
2. Tick The Necessary Rule Detail Below To Change Classification Rule					
(If more than one rule is applicable, th	e higher classific	ration shall apply)			
3. Risk Rule Available For Class A -					
Medical Device Intended Uses	Medical Device Intended Uses				
** NO LIST FOR MEDICAL DEVICE INTENDE	D USE FOR DEVI	CE			
Class A					

#### 2.1 CREATE CLASS APPLICATION

#### 2.1.1 CLASSIFICATION APPLICATION

Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.

=	Classification
De	vice Condition
	NEW REFURBISHED USED

Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.



Next, tick 'NON-INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type field.

Classification	
Device Condition	
NEW REFURBISHED USED	
Device Type	
GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE	
General Medical Device (GMD) Type	
NON-INVASIVE DEVICE INVASIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES	

After that, tick 'RULE 1' radio button in 'Non-invasive Device Rules' field.

vice Condition	
• NEW REF	JRBISHED USED
vice Type	
GENERAL MED	ICAL DEVICE IN VITRO DIAGNOSTIC MEDICAL DEVICE
neral Medical Device	GMD) Type
NON-INVASIV	DEVICE INVASIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES
n-invasive Device Ru	5

Next step, tick 'INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS' radio button at 'Rules 1 Details' field.

Device Type
GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE
General Medical Device (GMD) Type
NON-INVASIVE DEVICE O INVASIVE DEVICE O ACTIVE DEVICE O ADDITIONAL RULES
Non-invasive Device Rules
RULE 1 RULE 2 RULE 3 RULE 4
Rule 1 Details
MEDICAL DEVICE THAT IS INTENDED TO BE IN CONTACT WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF EXUDATE     INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS     THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT

## Medical Device Risk And Classification Details and Class Payment Details will be display. User

click Create Application to go to next step step.

one a Decards				
MEDICAL D EXUDATE	EVICE THAT IS INTENDED TO BE IN CO INTENDED PRINCIPALLY FOR WOUNI THE WOUND CAN BE BE HEAL ONLY	NTACT WITH INJURED SKIN AND INTE DS WHICH BREACH THE DERMIS THROUGH SECONDARY INTENT	NDED AS A BARRIER, OR FOR COMPRE	ISION, OR ABSORPTION OF
edical Device Risk	And Classification Details			
Based on your se Medical Device T Medical Device R Medical Device R Medical Device R	election, the Medical Device Risk Classificatio ype Risk Type Jule Detail Disk Class	In IS- IS- IS- IS- IS- IS- IS- IS-	E {GMD} - NON-INVASIVE DEVICE	
lass Payment Detai	ls			
The Medical Dev	DEVICE RISK TYPE		FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE	100.00
			APPLICATION FEE	250.00
CLASS B	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE	250.00
CLASS B	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE APPLICATION FEE	250.00 1000.00 500.00
CLASS B CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE APPLICATION FEE REGISTRATION FEE	250.00 1000.00 500.00 2000.00
CLASS B CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE REGISTRATION FEE APPLICATION FEE APPLICATION FEE	250.00 1000.00 500.00 2000.00 750.00
CLASS B CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE REGISTRATION FEE REGISTRATION FEE REGISTRATION FEE REGISTRATION FEE	250.00 1000.00 500.00 2000.00 750.00 3000.00
CLASS B CLASS C CLASS D	IN-VITRO, GENERAL MEDICAL DEVICE		APPLICATION FEE REGISTRATION FEE REGISTRATION FEE APPLICATION FEE REGISTRATION FEE REGISTRATION FEE APPLICATION FEE APPLICATION FEE	250.00 1000.00 500.00 2000.00 750.00 3000.00 750.00

#### 2.1.2 CLASS C APPLICATION

Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.

Γ	=	Classification
	Devis	ce Condition
		NEW REFURBISHED USED

Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.



Next, tick 'NON-INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.

E Classification
Device Condition
NEW      REFURBISHED      USED
Device Type
GENERAL MEDICAL DEVICE     OIN VITRO DIAGNOSTIC MEDICAL DEVICE
General Medical Device (GMD) Type
NON-INVASIVE DEVICE ACTIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES

After that, tick 'RULE 1' radio button in 'Non-invasive Device Rules' field.

evice Condition	
NEW      REFURBISHED      USED	
evice Type	
GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE	
eneral Medical Device (GMD) Type	
NON-INVASIVE DEVICE      INVASIVE DEVICE      ADDITIONAL RUL	ES
on-invasive Device Rules	

Next step, tick 'THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT' radio button at 'Rules 1 Details' field.

Device Type
GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE
General Medical Device (GMD) Type
NON-INVASIVE DEVICE O ACTIVE DEVICE ADDITIONAL RULES
Non-invasive Device Rules
RULE 1 RULE 2 RULE 3 RULE 4
Rule 1 Details
MEDICAL DEVICE THAT IS INTENDED TO BE IN CONTACT WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF     EXUDATE     INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS     THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT

## Medical Device Risk Classification Details field and Class Payment Details field will be display.

User click

Create Application to go to next step step.

MEDICAL D EXUDATE	EVICE THAT IS INTENDED TO BE INTENDED PRINCIPALLY FOR THE WOUND CAN BE BE HEA	E IN CONTACT W WOUNDS WHICH L ONLY THROUG	ITH INJURED SKIN AND INTEN H BREACH THE DERMIS H SECONDARY INTENT	IDED AS A BARRIER, OR FOR COMP	RESSION, OR ABSORPTION OF
dical Device Risk	And Classification Details				
Based on your a Medical Device Medical Device Medical Device Medical Device	election, the Medical Device Risk Cla Type Risk Type Rule Rule Detail Risk Class	ssification is :- : : : :	NEW GENERAL MEDICAL DEVICE RULE 1 The wound can be be heal o Class C Create Application	(GMD) - NON-INVASIVE DEVICE	
ss Payment Deta The Medical De	ils vice Risk Class Payment Are As Folk	9865-			
ss Payment Deta The Medical De CLASS	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE	9WS:-		FEE TYPE	AMOUNT (RM)
the Medical Detain CLASS	ils vice Risk Class Payment Are As Folix DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL	ows:-		FEE TYPE APPLICATION FEE	AMOUNT (RM) 100.00
the Medical De CLASS CLASS A	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL	www.		FEE TYPE APPLICATION FEE APPLICATION FEE	AMOUNT (RM) 100.00 250.00
ss Payment Deta The Medical Der CLASS CLASS A CLASS B	ils vice Risk Class Payment Are As Folio DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL	DEVICE		FEE TYPE APPLICATION FEE APPLICATION FEE REGISTRATION FEE	AMOUNT (RM) 100.00 250.00 1000.00
ss Payment Deta The Medical Der CLASS CLASS A CLASS B	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL	DEVICE		FEE TYPE APPLICATION FEE APPLICATION FEE REGISTRATION FEE APPLICATION FEE	AMOUNT (RM)  100.00  250.00  1000.00  500.00
ss Payment Detai The Medical Det CLASS CLASS A CLASS B CLASS C	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL	DEVICE DEVICE		FEE TYPE APPLICATION FEE APPLICATION FEE REGISTRATION FEE REGISTRATION FEE REGISTRATION FEE	AMOUNT (RM)  100.00  250.00  1000.00  500.00  2000.00
ss Payment Deta The Medical De CLASS CLASS A CLASS B CLASS C	ils vice Risk Class Payment Are As Folio DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL	DEVICE DEVICE		FEE TYPE APPLICATION FEE APPLICATION FEE APPLICATION FEE REGISTRATION FEE REGISTRATION FEE APPLICATION FEE APPLICATION FEE	AMOUNT (RM) 100.00 250.00 1000.00 500.00 2000.00 750.00
ss Payment Deta The Medical De CLASS CLASS A CLASS B CLASS C	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL	DEVICE DEVICE DEVICE DEVICE		FEE TYPE APPLICATION FEE APPLICATION FEE REGISTRATION FEE REGISTRATION FEE APPLICATION FEE REGISTRATION FEE REGISTRATION FEE REGISTRATION FEE	AMOUNT (RM)  100.00  250.00  1000.00  500.00  2000.00  750.00  3000.00
ss Payment Detai The Medical Det CLASS CLASS A CLASS B CLASS C CLASS C	ils vice Risk Class Payment Are As Follo DEVICE RISK TYPE IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL IN-VITRO, GENERAL MEDICAL GENERAL MEDICAL	DEVICE DEVICE DEVICE DEVICE		FEE TYPE         APPLICATION FEE         APPLICATION FEE         REGISTRATION FEE         REGISTRATION FEE         APPLICATION FEE         REGISTRATION FEE         APPLICATION FEE         APPLICATION FEE         APPLICATION FEE         APPLICATION FEE         APPLICATION FEE         APPLICATION FEE	AMOUNT (RM)  100.00  250.00  1000.00  500.00  2000.00  750.00  3000.00  750.00

#### 2.1.3 CLASS D APPLICATION

Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.

=	Classification
Devi	ice Condition
•	NEW REFURBISHED USED

Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.

=	Classification
Dev	ice Condition
	NEW      REFURBISHED      USED
Dev	ice Type
	GENERAL MEDICAL DEVICE     IN VITRO DIAGNOSTIC MEDICAL DEVICE

Next, tick 'INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.

Elassification
Device Condition
● NEW
Device Type
GENERAL MEDICAL DEVICE     OIN VITRO DIAGNOSTIC MEDICAL DEVICE
General Medical Device (GMD) Type
NON-INVASIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES

After that, tick 'RULE 6' radio button in 'Non-invasive Device Rules' field.

Classification
Device Condition
● NEW
Device Type
GENERAL MEDICAL DEVICE     OIN VITRO DIAGNOSTIC MEDICAL DEVICE
General Medical Device (GMD) Type
NON-INVASIVE DEVICE ACTIVE DEVICE ACTIVE DEVICE
Invasive Device Ru
© RULE 5 ● RULE 7 ● RULE 8

Next step, tick 'UNLESS THEY ARE INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH THE CENTRAL NERVOUS SYSTEM; OR' radio button at 'Rules 6 Details' field.

Invasive Device Rules
RULES RULE 6 RULE 7 RULE 8
Rule 6 Details
<ul> <li>SURGICALLY INVASIVE MEDICES DEVICES INTENDED FOR TRANSIENT USE</li> <li>UNLESS THEY ARE MEDICAL DEVICES ARE REUSABLE SURGICAL INSTRUMENTS (EXAMPLES: MANUALLY OPERATED SURGICAL DRILL BITS AND SAWS)</li> <li>UNLESS THEY ARE MEDICAL DEVICES THAT ARE INTENDED TO SUPPLY ENERGY IN THE FORM OF IONIZING RADIATION (EXAMPLE: CATHETER INCORPORATING/CONTAINING SEALED RADIOISOTOPES)</li> <li>UNLESS INTENDED TO HAVE A BIOLOGICAL EFFECT OR BE WHOLLY OR MAINLY ABSORBED (EXAMPLE : INSUFFLATION GASES FOR THE ABDOMINAL CAVITY)</li> <li>UNLESS INTENDED TO ADMINISTER MEDICINAL PRODUCTS BY MEANS OF A DELIVERY SYSTEM, IF THIS IS DONE IN A MANNER THAT IS POTENTIALLY HAZARDOUS TAKING ACCOUNT OF THE MODE OF APPLICATION (EXAMPLE: INSULIN PEN FOR SELF-ADMINISTRATION)</li> <li>UNLESS THEY ARE INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH THE CENTRAL NERVOUS SYSTEM; OR</li> <li>UNLESS INTENDED SPECIFICALLY TO DIAGNOSE, MONITOR OR CORRECT A DEFECT OF THE HEART OR OF THE CENTRAL CIRCULATORY SYSTEM THROUGH DIRECT CONTACT WITH THESE PARTS OF THE BODY</li> </ul>

## Medical Device Risk And Classification Details and Class Payment Details will be display. User

click Create Application to go to next step step.

Based on your s	election, the Medical Device Risk C	lassification is :-			
Medical Device	lype	1	NEW		
Medical Device	Risk Type	:	GENERAL MEDICAL DEVICE	(GMD) - INVASIVE DEVICE	
Medical Device	Rule	-	RULE 6		
Medical Device I	tule Detail Rick Class		Unless they are intended sp	pecifically for use in direct contac	t with the central nervous system; or
			Create Application		
s Payment Detai The Medical Dev	ls rice Risk Class Payment Are As Fo	lows-			
CLASS	DEVICE RISK TYPE			FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDIC	AL DEVICE		APPLICATION FEE	100.00
0.653	IN ATTOC CENTERS MEDIC	H DEVICE		APPLICATION FEE	250.00
CLASS B	IN-111HD, DENERAL MEDIC	AL DEVICE		REGISTRATION FEE	1000.00
CLASS C	IN ATEO GENERAL MEDIC	N DEVICE		APPLICATION FEE	500.00
CD/33 C	IN TITNO, GENERAL REDIO	AL DEVICE		REGISTRATION FEE	2000.00
	NUMBER OF STREET	H DEVICE		APPLICATION FEE	750.00
C1 455 D	IN-ITTRU, GENERAL MEDIC	AL DEVILE		REGISTRATION FEE	3000.00
CLA35 D				APPLICATION FEE	750.00
	GENERAL MEDICAL DEVICE			1	

#### **2.2 FILL IN THE APPLICATION FORMS**

## 2.2.1 1.0 ESTABLISHMENT DETAILS

MCDCOSt v2.0	Quick Search Q. Advanced Search	🔳 ENGLISH 🔹 🐥	(2) - Example El name - MOHD FARIQ -
💼 номе 🗸 🛨	III Medical Device Registration (MDR-20171118-344)		
💼 ESTABLEHMENT LICENSE 🔹 👻	1.1 Establishment Details		N Application Detail
ACCOUNT MANAGEMENT	1. BUSINESS REG NO	MDR_01	1.0 ESTABLISHMENT DETAILS
O ONLINE HELP -	2. ESTABLISHMENT NAME	MOHD FARIQ	2.0 GENERAL INFORMATION 3.0 MEDICAL DEVICE GROUPING
	3. NAME OF PERSON RESPONSIBLE	ABDUL MALIK BIN MCHAMED	4.0 CSDT
			5.0 MANUFACTURER INFORMATION
	4. ADDRESS	UNLAKA RESOURCES SON BHD D-9-5, MEGAN AVENUE 1, 189	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
		KUALA LUMPUR	7.0 CONFORMITY ASSESSMENT
	5. EMAIL	aidil00ex@gmail.com	8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
	6. TELEPHONE NO	603-21666558	4 A RECI ABATION OF CONFORMITY 4
	7. NAME OF CONTACT PERSON	ABDUL MALIK BIN MCHAMED	
	wer     construction     wer     construction     construction     construction     construction     construction     construction		BGUR - A (1)- S Desphiltness HORING MM_M.
		1. TUTALUP-RENT MAR	ND-0 MAQ ND-0 MAX BIN ROWARD
Hide the side	ebar for full	4.0000	Industry Reconstruction (Inc) Red, Million Andread I, Jan And Through Angeler Reconstruction (Inc)
display		3.13865	aut/Over@gmat.com
i		4. 10.104-004 ND	80-1398008
		1. MARE OF CONTACT PERSON	ABOUL INALM BELINDMANED

Next 🌖 User unable to edit this section, this section only display for user. User click to the next step.

to go

### 2.2.2 2.0 GENERAL INFORMATION

#### 2.2.2.1 GMD APPLICATION

Users need to complete all fields.

Medical Device Registration (MDR-20171116-344)		
General Information		Application Detail
1. Role Of Establishment To Nedical Device	Manufacturer     Authorized Representative	1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
2. Medical Device Name * 🖗		3.0 MEDICAL DEVICE GROUPING
	4	+ 4.0 CSOT
3. Class Of Device	CLASS B	5.0 MANUFACTURER INFORMATIO
		6.0 PRE-MARKET CLEARANCE/PRE
4. Device Risk Type	GENERAL MEDICAL DEVICE - NON-INVASIVE DEVICE	MARKET APPROVAL
5. Classification Bules	BULLET 1	7.0 CONPORMITY ASSESSMENT
a Caratinoni Hunca	TIME A	AND VIGILENCE
6. Proprietary Name/Brand *		6 ODECLADATION OF COMEDENIN
7. Medical Device Category * O	-Select Medical Device Category-	*
	Scheet Medical Device Unlegary     MO 0100 - GENERAL NOV-ACTIVE, NON-ARTHUR MEDICAL DEVICES     MO 0100 - Non-active orbitopaetic and inshalifiation devices     MD 0101 - Non-active devices for assauthesis, emergency and Intensive care     MD 0102 - Non-active devices for insection, infraution, Interdiation devices     MD 0103 - Non-active ophthalmologic devices     ND 0105 - Non-active ophthalmologic devices     MD 0109 - Non-active medical devices with measuring function     MD 0109 - Non-active medical devices     MD 0109 - Non-active encloses for disinfecting, cleaning and rinsing     MD 0109 - Non-active encloses     MD 0109 - Non-active encloses     MD 0202 - Non-active encloses     MD 0202 - Non-active enthopsecial implants     MD 0202 - Non-active enthopsecial implants     MD 0202 - Non-active enthopsecial implants     MD 0202 - Non-active soft Soure implants     MD 0202 - Non-active soft Soure implants     MD 0203 - Non-active enthopsecial implants     MD 0203 - Non-active soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0203 - Reserved Soft Soure implants     MD 0203 - Reserved Soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0203 - Reserved Soft Soure implants     MD 0203 - Reserved Soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0203 - Reserved Soft Soure implants     MD 0204 - Non-active soft Soure implants     MD 0204 - N	chnologies (ART)

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Module Utama MDR Class B,C & D Medical Device Centralised Online Application System (MeDC@St 2.0)

Conformity Assessment Procedures Exempted For Export Only	Nedical Device
	Click for downloadfile
Lupload file Supported File Type : Pdf	
Uploaded Files :-	
TEST.pdf	A ×
	Click for
Name of file will show here Click to view file	remove file
-	Ves No Ves No Ves No Ves No N

User click to upload file'. The file must be pdf format and size not more than

300 MB.

Medical	Device Authority,	Ministry of	f Health	Malaysia	User	Manual Front	End Us	ser - Module	Utama M	DR Class B,C	& D
				Medical	Device	Centralised	Online	Application	System	(MeDC@St 2	2.0)

10. is Th	e Medical Device Con	tains Any Active Ingredient, Pois	on Or Drug <sup>*</sup> 😡	8 Yez 0 Ko			
+ Ads	1Active Ingredient/Pois	on/Drug				1	Application Detail
Showing	1-1 of 1 item.						1.0 ESTABLISHMENT DETAILS
No	Ingredient	Scientific Name	Ingredient Function	Quantity	Composition Percentage (%)	Action	2.0 GENERAL INFORMATION
1	XXX	XXX	XXX	90	90	E Deide	5.0 MEDICAL DEVICE GROUPING
LL. Desc	ription of medical de	vice " 🖗					4.0 CSDT
						li.	S.0 MANUFACTURER INFORMATIO
12. Inter	ided Use of Medical D	levice "O					6.0 PRE-MARKET CLEARANCE/PRE MARKET APPROVAL
	0050						7.0 CONFORMITY ASSESSMENT
13. 115-0	0000						8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
14. GMD	N CODE 😡						
15. Uniq	ue Device Identifier ()	UDI) Code 😡					
L6. UMD	NS Code						
• •	revious	Active Ingredients/Poisse/Drug			×	Net 🔶	
	_	Insert Active Instedient Polson/Dru					
		3. Ingredient :					
		1. Scientific Name :					
	<b>`</b>	3. Ingredient Function (					
		4. Quantity :					
		5. Competition Percentage :					
					Salaria		
	L						
		+ Add Active I	ngredient/Poison/D	rug			
•	Click			to a	add active ingredien	t/poison/dru	ig details. Then
			Submit				
	fill the f	form and the	n click				
		Delete					
•	Click	to	delete data in t	the table.			
	<u>-</u>	Next 🍝					
٠	Click	INCAL 7	o go to the ne	xt sectior	l.		
		a state					
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#### 2.2.2.2 IVD APPLICATION

Users need to complete this form

Medical Device Registration (MDR-20171120-358)		
2.1 General Information		Application Detail
1. Role Of Establishment To Medical Device	Manufacturer Authorized Representative	1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
2. Medical Device Name * 🚱		3.0 MEDICAL DEVICE GROUPING
		4.0 CSDT
3. Class Of Device	CLASS B	5.0 MANUFACTURER INFORMATION
4. Device Risk Type	IN VITRO DIAGNOSTIC MEDICAL DEVICE	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
		7.0 CONFORMITY ASSESSMENT
5. Classification Rules	RULE 4	8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
6. Proprietary Name/Brand *		
7. Medical Device Category * 😡	-Select Medical Device Category-	*
Advised Mediated Service George y     (VD 02020 List & Resugents And Beagents Products,     (VD 02021 Results) [5, -5, 0, 1, 6]     (VD 02021 Results) [6, -6, 0, 1]     (VD 02021 Results) [7, 0, 0, 0, 1]     (VD 02021 Resu	Including Belated Calibrators And Control Materials, For Determining The Polloving Blo Including Belated Calibrators And Control Materials, For The Detection, Confirmation A Devices For Self - Diagnosis, Including Belated Calibrators And Control Materials, For De procisi	nd Groups *

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8. Is the device meant for export only? * 😡	⊖ Yes ⊛ No	
	Conformity Assessment Procedures Exempted For Export Only Medical	Application Detail
9. Description of medical device *		1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
10. Intended Use of Medical Device * 😡		3.0 MEDICAL DEVICE GROUPING
		4.0 CSDT
11. HS CODE 🖗		5.0 MANUFACTURER INFORMATION
12. GMDN CODE 😡		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
		7.0 CONFORMITY ASSESSMENT
13. Unique Device Identifier (UDI) Code 🖗		8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
14. UMDNS Code		
+ Previous	Nest 🔶	



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#### 2.2.3 3.0 MEDICAL DEVICE GROUPING

#### 2.2.3.1 GMD APPLICATION

Users have to complete all fields.

Medical Device Registration (MDR-20171116-344)	)			-	Application Detail
3.1 Medical Device Grouping (GMD)					L0 ESTABLISHMENT DETAILS
GROUPING TYPE OF MEDICAL DEVICE :		-Pick Grouping Type-		*	2.0 GENERAL INFORMATION
Release Review Versities a Planae Tee Present One a Rev Tee Hardeni Prese	-				3.0 MEDICAL DEVICE GROUPING
Presse shake hav note chosen the carries when your the residue way			]		4.0 CSDT
Previous			Nex	•	5.0 MANUFACTURER INFORMATION
Single System	g Type-				6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
Family Set					

User select 'Single', 'System', 'Family' or 'Set'.

#### i) Single

Medical Device Registration (MDR-20171116-344)		>	Application Detail
3.1 Medical Device Grouping (GMD)			LOPSTARI ISHMENT DETAILS
GROUPING TYPE OF MEDICAL DEVICE :	Single		2.0 GENERAL INFORMATION
"Manua Secure Versions Chrose The Propert Secure Sec The Madded Review		-1	3.0 MEDICAL DEVICE GROUPING
Prevent annual in the Prevent structure and the second structure from the interview second			4.0 CSDT
DEVICE IDENTIFIER:	Insert Identitifer		5.0 MANUFACTURER INFORMATION
+ Previous	Next 🔶		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
			7.0 CONFORMITY ASSESSMENT
			8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
Jser fill 'DEVICE IDENTIFIER' textbox	x'. Click Next ➔ to go to th	e n	ext section. Click

## ii) System

	(10-344)		<u> </u>	Application De	tail
Medical Device Grouping (GMD)				1.0 ESTABLISHMENT DET	TAILS
GROUPING TYPE OF MEDICAL DEVICE :		System		2.0 GENERAL INFORMATI	ION
				3.0 MEDICAL DEVICE GRO	OUPING
"Please Insert Medical Device Name On 2.0 General Informati	ion Item No 3			4.0 CSDT	
"Please Ensure You Have Chosen The Correct Group For The I	Vedical Device			5.0 MANUFACTURER INF	ORMATIO
No System Name/Model	Action			6.0 PRE-MARKET CLEARA MARKET APPROVAL	NCE/PRE
1	Q View	Device GP Add Device		7.0 CONFORMITY ASSESS	SMENT
🔶 Previous			Next 🔶	8.0 POST-MARKET SURVE	EILLANCE
				AND VIGILENCE	
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Invite Graphing IN. BEPROE USE Internet Of Factors, Manual Of Devices, Constituent Components, Accesses fass, Reagents On Articles, Re Per Product Label Device X	Davlas Brid Dasciption Meetiliae Rem 12068 Campie	Notified Strike Stronging           Notified Stronging	Rear (sol, to to ) Regulation Regulation Research Manual Provider State Research		
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- Click Click Click Click to add new device. *Medical Device Grouping* field will display.
- Click **Q** View Device to view device.

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	(SHOP (UP, DA) HEDICAL DEVICE GROUPING     (SHOP HIGH CONTRACT AND A CONTRAC
	[Cool for CHD-Sphere, Set and YO Test KD, Family ] 2. All in the form
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	MEDICAL DEVICE LAST
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Showing 6-4 of Liters, Name Of Desice, Constituent Components, Accessories, Reagants Desice Beacrystem Of	Name Of Device, Constituent Components, Accessories, Reagents Device Description Of Action O No. Or Articles As Por Product Label Action O
No 07 Articles As Par Product Label Identifier Item Action II 1 Decisit X 12458 Europe III III III III III III III III III I	1 Device X 123456 Example 2 D
User click     Add Device Manually     , the     add device.	en user have to fill the form and click Submit to
User click	(LS, XLSX), user have to upload file. User click
to upload excel file. The	e file must be xlsx or xls format.
<ul> <li>button for user edit device detail</li> </ul>	ils.
• <b>I</b> button for user delete device.	
DELETE SELECTED     button to delete	e selected data in the table.
Click     Next      to go to the next s	section.
Click     Previous     to go to the previous	ous section.

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iii) Family

		1.0 ESTABLISHMENT DETAILS			
UPING TYPE OF MEDICAL DEVICE : Family		2.0 GENERAL INFORMATION			
		3.0 MEDICAL DEVICE GROUPING			
Family	•	4.0 CSDT			
Please insert Hedical Device Name On 2.0 General Information Item No 3 Permity Of System		5.0 MANUFACTURER INFORMATION			
		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL			
		7.0 CONFORMITY ASSESSMENT			
		8.0 POST-MARKET SURVEILLANCE AND VIGILENCE			
	Next 🌩				
	Family Family Family Of System	Family * Family Family Of System			

For GROUPING TYPE OF MEDICAL DEVICE, user select between 'Family' or 'Family Of System'.

a) Family

						-	Application Detail
Medical Device Grouping (GMD)							1.0 ESTABLISHMENT DETAILS
			1				
GROUPING TIPE OF MEDICAL DEVICE :			Family			•	20 GENERAL INFORMATION
			Read to				3.0 MEDICAL DEVICE GROUPING
			ramiy			•	4.0 CSDT
"Mease Insert Medical Device Nome On 2.0 General Information	Item No 3						5.0 MANUFACTURER INFORMATIO
"Please Ensure You Have Chosen The Correct Group For The He	dical Device						6.0 PRE-MARKET CLEARANCE/PR MARKET APPROVAL
No Action							T.0-CONFORMITY ASSESSMENT
1 Q, View Device DF Add Device							8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
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- Click Add Device to add new device. Medical Device Grouping field will display.
- Click View Device to view device.

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• button for user delete device.		
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• Click to go to the next sect	tion.	

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# b) Family Of System

Medical Device Grouping (GMD)			<b>`</b>	Application Detail
GROUPING TYPE OF MEDICAL DEVICE :	Family		*	1.0 ESTABLISHMENT DETAILS
				2.0 GENERAL INFORMATION
	Family Of Syster	m	*	3.0 MEDICAL DEVICE GROUPING
"Mease Insert Hedical Device Name On 2.0 General Information Item No 3				4.0 CSDT
"Please Braune You Have Chosen The Connect Droug For The Realizal Device				5.0 MANUFACTURER INFORMATI
+ Add System Name/Wodel				6.0 PRE-MARKET CLEARANCE/P MARKET APPROVAL
No System Name/Model		Action		7.0 CONFORMITY ASSESSMENT
No results found.				8.0 POST-MARKET SURVEILLANK AND VIGILENCE
🔶 Previous			Next 🔶	
Medical Device Grouping		н		
Family of System				
1. INSERT SYSTEM NAME; MODEL :				

Click	+ Add System Name/Model	to new	system	name o	r model.	User fill	the form	and click
Subr	nit							

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No	System Name/Model				Action						
1	Model X				Q View De	e 🕼 Add Device 💼 Delete					
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HIDEAL D	EVER LET					ADD DEVICE FOR Mudel 2					
No. N	d of Liters. anne Ol Davice, Constituent Components, Accessories, angents Dr Articles An Per Product Label	Pesnisalitie Verlent	Details on Permisaible Variant	Device Montifier	Drief Description Of hom	+ Add Device Hermally & Option Herbral Device ( 8,5, 12, 19 UPL:040 DEVICE UPL &					
1 9	nua A	Variant 8		2.04.041		[BROWLFLORD MEDICAL DEVICE GROUPING] L. Download Thengliste for Hedical Device Grouping below [Gamilian Gamilian System, Set and HD Yoot KD, Family.]	1	liphond Mic 195 Alf Life Children Jac aparted Mic Types 35	EL PILI WILL DE N. Xh	LETTE ACL DESTIN	6 24
						2.100 in the form 3.11pland	Upier N	alied files r o Uploaded files			
						MEDICAL DEVICE UST					
						Name Of Device, Constituent Components, Accessaries, Reagents Or Articles An Per No. Product Label No results found.	Permissible Variant	Details on Permissible Variant	Device Identifier	Brief Description Of item	4

- Click Add Device to add new device.
- Click **Q** View Device to view device.
- Click Delete to delete data in the table.

Medical Device Grouping	×
ADD DEVICE FOR Model X	
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ADD DEVICE MANUALLY	
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	i
+ Add Device Manually	Submit
User click     then use	er have to fill the form and click to
add device.	
Upload Medical Device [XLS, XLS	X] user have to unload file. User click
<sup>1</sup> Upload file to upload excel file. The file	must be visy or vis format
button for user edit device details	
<ul> <li>button for user delete device.</li> </ul>	
• DELETE SELECTED button to delete selected	cted data in the table.
<ul> <li>Click</li> <li>Next &gt; to go to the next section</li> </ul>	n.


iv) Set

1 Medical Device Grouping (GMD)					1.0 ESTABLISHMENT DETAILS
GROUPING TYPE OF MEDICAL DEVICE :		Set			2.0 GENERAL INFORMATION
					3.0 MEDICAL DEVICE GROUPING
"Please insert Hedical Device Name On 2.8 General Information Item N	3				4.0-CSDT
messe answe not more chosen the correct arough or the mession of					5.0 MANUFACTURER INFORMATION
No System Name/Model	Action	n			6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
1	C( Vi	W Device Of Add	evka		7.0 CONFORMITY ASSESSMENT
Previous				Next 🔶	8.0 POST-HARKET SURVEILLANCE AND VIGILENCE
Invice Grouping			ן		
AL DEVICE LIST			Hedical Device Grouping		
			A00 0694(2 FDB		
Name Of Device. Constituent Components, Accessories, Respects Or Articles Per Psodest Label	An Denice 0 Meetiller In	hief Description Of lans	• Add Series Hermity Lipland Herbert Series ( 0.5	(10.00)	
Device 5ET	527 8	87	UPLINE DEVICE LIKE &		
			(BETOTOPORO MERCA, DEACE BROUPAS) 1. Soundhard Template for Westball Social Grouping Solver (Deach for ONE - System, Set and Yell Text 40, Family)	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	na un long ginter file wegi delette all gordning gada tila type: tila til
			2. Ellin the form 3. Upland	Liphonded P	las.»
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			MEDICAL DEVICE LIET		

- Click Add Device to add new device.
- Click **Q View Device** to view device.

Medical Device Grouping		×
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+ Add Device Manually  Lupload Medical Device [XLS, XLSX]		
ADD ODVICE MARKALLY	UPLING DENCE LIFE &	
Rame IV Bevin, Conditions Components, Accessories, Reagents In Intelligence Per Product Labor	(BATCH UPLEAR HER GRUNDWEET GROUPING)	A Option Proc.
Permissible Review.	1. Download Template for Weshcat Device Tocopring before ( Easel for UMD - Typines, Tel and ND Test KB, Facelly )	<ul> <li>Equipment of the System State, State</li> </ul>
	2. Fill in the form 2. Splead	Rybached Film -
Belaits on Permissible Variant		No (granted Fine
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and pand which as used	Name Of Device, Constituent Components, Accessorie No Or Articles As Per Product Label	in, Response Device Drief Description Meetifier Officer Action D
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and a second		
HEROR, DENCE UST		
Construction     C		
User click add device.	er have to fill the for	m and click Submit to
User click	x], user have to	upload file. User click
▲ Upload file to upload excel file. The file	must be xlsx or xls f	format.
• Dutton for user edit device details.		
<ul> <li>button for user delete device.</li> </ul>		
• DELETE SELECTED button to delete selected	cted data in the table.	
Click     Next      to go to the next section	n.	
Click     Previous     to go to the previous se	ection.	

## 2.2.3.2 IVD APPLICATION

	-Pick Grouping Type-	
	Single System Family Set IVD Test Kit IVD Cluster	
Medical Device Registration (MDR-20171120-	358)	N Application Detail
1 Medical Device Grouping (IVD)		1.0 ESTABLISHMENT DETAILS
GROUPING TYPE OF MEDICAL DEVICE :	-Pick Grouping Type-	2.0 GENERAL INFORMATION
"Please Ensure You Have Chosen The Correct Group For The Hedic	of Device	3.0 MEDICAL DEVICE GROUPING 4.0 CSDT
DISCIPLINE	-SELECT-	5.0 MANUFACTURER INFORMATION
CATEGORY	-SELECT-	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
Previous		7.0 CONFORMITY ASSESSMENT Next
SULLCT Engmes Substrates Electrolytes Reagents Electrolyte Electrodes Substrate Electrodes Substrate Electrodes	-SELECT Clinical Chemistry Immunochemistry Haematology (Blood tests for transfusions Histology/Cytology Microbiology Microbiology	ABATION OF CONFORMITY excluded)

User select from 'Single', 'System', 'Family', 'Set', 'IVD Test Kit' or 'IVD Cluster'.

For IVD application, there to additional question, 'DISCIPLINE' and 'CATEGORY'. Data from 'CATEGORY' will change according to the selected data in 'DISCIPLINE'.

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# i) Single

Medical Device Registration (MDR-20171120-358)	<u> </u>	Application Datail				
		2	Application Detail			
3.1 Medical Device Grouping (IVD)		1.0 ESTABLISHMENT DETAILS				
GROUPING TYPE OF MEDICAL DEVICE :	Single		2.0 GENERAL INFORMATION			
"Please Ensure You Have Chosen The Correct Group For The Medical Device	*Please Fasure You House Chosen The Connect Group For The Medical Device					
			4.0 CSDT			
DEVICE IDENTIFIER :	Insert Identitifer		5.0 MANUFACTURER INFORMATION			
DISCIDEINE	-SELECT.	_	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL			
DIDUT CITL.	-9666-01-		7.0 CONFORMITY ASSESSMENT			
CATEGORY	-SELECT-		8.0 POST-MARKET SURVEILLANCE			
+ Previous	Next -	•				

User complete Device IDENTIFIER, DISCIPLINE and CATEGORY filed.



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# ii) System

1 Medical Device Grouping (IVD)				Application Detail
GROUPING TYPE OF MEDICAL DEVICE :			System	1.0 ESTABLISHMENT DETAILS
				2.0 GENERAL INFORMATION
"Places Insert Medical Device Nome On 2.0 Gene	3.0 MEDICAL DEVICE GROUPING			
		-		4.0 CSDT
SAME MANUFACTURER			Yes 🔘 No	5.0 MANUFACTURER INFORMATION
DISCIPLINE			-SELECT-	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
CATEGORY			-SELECT-	7.0 CONFORMITY ASSESSMENT
				8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
No System Name/Model		Action		9 // DECLARATION OF CONFORMITY
1		Q View	evice CP Add Device Healter Breat Breat Coupling	
			ABD DRIVES FOR	
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			HEROM, DOVICS USF	

- Click Add Device to add new device.
- Click **Q View Device** to view device.

Medical Device Grouping		×
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# iii) Family

edical Device Grouping (ND)		<b>_</b>	Application becan
GROUPING TYPE OF MEDICAL DEVICE :	Family		1.0 ESTABLISHMENT DETAILS
			2.0 GENERAL INFORMATION
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Please Insert Medical Device Name On 2.0 General Information Idem No 3	Family Family Of System		4.0 CSDT
Wease Ensure You Have Chasen The Correct Droup For The Hedical Device	5.0 MANUFACTURER INFORMATION		
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DISCIPLINE	-SELECT-		7.0 CONFORMITY ASSESSMENT
			8.0 POST-MARKET SURVEILLANCE
DATEGORY	-SELECT-		
			4
No Action			

Additional drop text box will appear, user select between 'Family' or 'Family Of System'.

a) Family

Medical Device Registration (MDR-20171120-358)		
3.1 Medical Device Grouping (IVD)		Application Detail
GROUPING TYPE OF MEDICAL DEVICE :	Pamily	1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
	Pamily	3.0 MEDICAL DEVICE GROUPING
"Please Insert Hedical Device Nome On 2.0 General Information Item No.3		4.0 CS0T
"Please Ensure You Hove Chosen The Correct Group For The Medical Device		5.0 MANUFACTURER INFORMATION
SAME MANUFACTURER	® Yes ◎ No	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
DISCIPLINE	-SELECT-	T.D CONFORMITY ASSESSMENT
		8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
CATEGORY	-SELECT-	
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• DELETE SELECTED button to delete selected data in the table.	
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b) System

Medical Device Registration (MDR-20171120-358)			
3.1 Medical Device Grouping (ND)		•	Application Detail
GROUPING TYPE OF MEDICAL DEVICE :	Family	٣	LO ESTABLISHMENT DETAILS
			2.0 GENERAL INFORMATION
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"Please Ensure You Have Chosen The Correct Group For The Medical Device			5.0 MANUFACTURER INFORMATION
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			8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
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	click	Submit

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- Click Add Device to add new device.
- Click **Q View Device** to view device.
- Click Delete to delete data in the table.

Medical Device Grouping		×
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iv) Set

Medical Device Registration (MDR-20171120-358)			
fedical Device Grouping (IVD)		•	Application Detail
GROUPING TYPE OF MEDICAL DEVICE :	Set	_	1.0 ESTABLISHMENT DETAILS
			2.0 GENERAL INFORMATION
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DISCIPLINE	-SELECT-		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
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- Click Add Device to add new device.
- Click **Q View Device** to view device.

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v) IVD Test Kit

Medical Device Grouping (IVD)				Application Detail
GROUPING TYPE OF MEDICAL DEVICE :		ND Test Kit		1.0 ESTABLISHMENT DETAILS
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Medical Device Authority, Ministry of Health Malaysia Medica

vi) IVD Cluster

Medical Device Grouping (IVD)				- <b>&gt;</b>	Application Detail
GROUPING TYPE OF MEDICAL DEVICE :		IVD Cluster			1.0 ESTABLISHMENT DETAILS
"Please Ensure You Have Chosen The Correct Group For The I	fedical Device				2.0 GENERAL INFORMATION
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INTENDED PURPOSE OF SUBGROUP				Substrate	Electrodes, Biosensors



to new system name or model. Fill the form and then





## 2.2.4 4.0 CSDT

\*\*This form not available if user GROUPING TYPE OF MEDICAL DEVICE is IVD Cluster.

Medical Device Registration (MDR-20171116-344)	
COMMON SUBMISSSION DOSSIER TEMPLATE (CSOT)	Application Detail
R C507	1.0 ESTABLISHMENT DETAILS
1 5507	2.0 GENERAL INFORMATION
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## 2.2.5 5.0 MANUFACTURER INFORMATION

User have to complete all field.

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5. Name Of Legal Manufacturer :	1.0 ESTABLI	SHMENT DETAILS
	2.0 GENERA	L INFORMATION
2. Address Of Legal Hanufacturer i	1.0 MEDICA	L DEVICE GROUPING
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- Click Update to update data in table.
- Click Delete to delete data in table.

# 2.2.6 6.0 PRE-MARKET CLEARANCE/ PRE-MARKET APPROVAL

<b>≡</b> Media	cal Device Registration ( MDR-20171116-344 )	
6.1 PRE-MAR	KET CLEARANCE/PRE-MARKET APPROVAL	Application Detail
Please indi	cate whether the medical device has obtained Pre-Market Clearance / Pre-Market Approval or considered Exempted/Not/Fied/Self-Declared from foreign countries	1.0 ESTABLISHMENT DETAILS
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User tick any check box above.(If necessary)

alia TGA								<b>`</b>	Application Detail
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## 2.2.7 7.0 CONFORMITY ASSESSMENT

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#### 2.2.8 8.0 POST-MARKET SURVEILLANCE AND VIGILENCE

User have to complete the field.

Medical Device Registration (MDR-20171116-344)		~	Application Detail
8.1 POST-MARKET SURVEILLANCE AND VIGILENCE			
<ol> <li>History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box)</li> </ol>	© Yes ⊛ No		1.0 ESTABLISHMENT DETAILS     2.0 GENERAL INFORMATION     3.0 MEDICAL DEVICE GROUPING
2. Has the application/registration been rejected/suspended in other countries?	© Yes ⊛ No		4.0 CSDT 5.0 MANUFACTURER INFORMATION 6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
3. Any ongoing Post-Market Issues?	© Yes ⊛ No		7.0 CONFORMITY ASSESSMENT 8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
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<ol> <li>History of previous recalls, reportable adverse incidents, bannin other countries or post market surveillance studies (Please check to appropriate box)</li> </ol>	g in he Yes No
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2. Has the application/registration been rejected/suspended in other countries?	Yes
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	Please upload Post-Market surveillance and vigilance report
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## 2.2.9 9.0 DECLARATION OF CONFORMITY

medical befree neglistration (mon-zozrazzo otto)		Application Detail
DECLARATION OF CONFORMITY		
		4.0 CSDT
Declaration of Conformity shall be prepared in accordance with the format in Appendix 3 of 3rd Schedule Medical Device Regulation 2012	Please upload Declaration of Conformity	5.0 MANUFACTURER INFORMATION
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## 2.2.10 10.0 ATTESTATION

Medical Device Registration (MDR-20171118-344)	>	Application Detail
10.1 ATTESTATION		4.0 CSDT
I, the Manufacturer/Authorized Representative of this/these device(s), hereby declare that :		5.0 MANUFACTURER INFORMATION
This product is a medical device according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737)		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
Is hall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and perforting these medical device(s).	rmano	7.0 CONFORMITY ASSESSMENT
<ul> <li>I hereby attest that the information and attachment provided on this application is/are accurate, correct, complete and current to this date.</li> <li>I inderstand and acknowledge that it is an offence under Section 76, of Act 737 to make sign or furnish any declaration, or other document with the information of the i</li></ul>	ich is	8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
Intrue, inaccurate or misleading.		9.0 DECLARATION OF CONFORMITY
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User have to tick all the checkbox before user can submit application. User click

Q PREVIEW & SUBMIT

to preview before submit application.
The diagram below will appear after user click [PREVIEW AND SUBMIT] button.

MDR Class B,C,D Application	
1.0 Establishment Details Click To View More	Complete
2.0 General Information Click To View More Status	Complete
3.0 Medical Device Grouping Click To View More	Complete
4.0 CSDT Click To View More Click to see more details about form	Complete
5.0 Manufacturer Information Click To View More	Complete
6.0 Pre-Market Clearance/Pre-Market Approval Click To View More	Complete
7.0 Conformity Assessment Click To View More *Conformity Assessment Dont Need To Be Filled If Device Is For Exportation	Complete
8.0 Post-market Surveillance And Vigilence Click To View More	Complete
9.0 Declaration Of Conformity Click To View More	Complete
10.0 Attestation Click To View More	Complete
Click to submit application	



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### 3.0 RE-REGISTRATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



The diagram below show Application List page. Click

to re-register application.

=	Medical Devi	ce Registration							
FILTER APPLICATION									
Showi	ng 1-1 of 1 item.								
No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR- 20171116- 344	NEW REGISTRATION	09-12-2017	MANUFACTURER	DEVICE Y IVD	в	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	Q View C ReRegister PAdvice & Receipt Withdrawal Certificate C Change Notification

🔁 ReRegister

# Next, user will go to 2.0 GENERAL INFORMATION page. User have to complete all fields with

(\*). User click to go to the next step.

Medical Device Registration (MDR-20171213-4	21)	
General Information		Application Detail
1. Role Of Establishment To Medical Device	Manufacturer Authorized Representative	VIEW PREVIOUS APPLICATION
2. Medical Device Name * 😡	DEVICE Y IVD	1.0 ESTABLISHMENT DETAILS 2.0 GENERAL INFORMATION
		3-0 MEDICAL DEVICE GROUPING
3. Class Of Device	CLASS B	4.0 CSDT
4. Device Risk Type	GENERAL MEDICAL DEVICE - NON-INVASIVE DEVICE	5.0 MANUFACTURER INFORMATION
		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
5. Classification Rules	RULE 1	7.0 CONFORMITY ASSESSMENT
6. Proprietary Name/Brand *	NAME YY	8.0 POST-MARKET SURVEILLANCE
7. Medical Device Category * 🖗	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDIC	ALD *
	MORTON ALL REPORT	×
	La Datable descel Details (2015) Street Series	Compiled I
	2.17 Dense of Informations (CDITED System Dates)	(Complete)
	2.3 Nodest Desize Scouping (23.3 Styles Same	Congress
	5.1 Reading on the matter	Compte
	1.2 For Harlet Conserve Per Harlet Approved 1233 in these house	Complete
	T.B. Cardierally, Rangement (2003) Richard Marry "Colorady Assessment from World So Alled	ribevia a ner bevortation
	1.0 Part-rapid Somelitance And Piplican Distribution Inco.	(Second
	3.4 Beckendler (M Contendity Child Editors)	Congress
	The Brokelow Distance of the Second	Computer

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

Medical Device Registration (MDR-20171213-421)			
		<b>&gt;</b>	Application Detail
3.1 Medical Device Grouping (GMD)			VIEW PREVIOUS APPLICATION
GROUPING TYPE OF MEDICAL DEVICE :	Single		1.0 ESTABLISHMENT DETAILS
*Please Ensure You Have Chosen The Correct Group For The Medical Device			2.0 GENERAL INFORMATION
			3.0 MEDICAL DEVICE GROUPING
DEVICE IDENTIFIER :	MEDICAL BRAND Y		4.0 CSDT
. Remaining			5.0 MANUFACTURER INFORMATION
Previous Next			6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
			7.0 CONFORMITY ASSESSMENT
			8.0 POST-MARKET SURVEILLANCE

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

The diagram below show 4.0 CSDT form. User have to fill all fields with (\*).

Medical Device Registration	(MDR-20171213-421)			
.0 COMMON SUBMISSSION DOSSIER TE	MPLATE (CSDT)		Application Detail	
CSDT				ON
1. CSDT		Lupload file Supported File Type : Pdf	1.0 ESTABLISHMENT DETAILS	
			2.0 GENERAL INFORMATION	
		Unloaded Files -	3.0 MEDICAL DEVICE GROUPING	
		TEST.pdf	4.0 CSDT	
			5.0 MANUFACTURER INFORMATIC	DN .
Executive Summary			6.0 PRE-MARKET CLEARANCE/PR MARKET APPROVAL	E.
			7.0 CONFORMITY ASSESSMENT	
EPSP EPSP			8.0 POST-MARKET SURVEILLANCE	E
3. EPSP	X V () Interform X X X X X X X X X X X X X	Lupload file Supported File Type : Pdf		
ck Upload file to	upload. The file	must be pdf format and s	size not more than 300	МІ
er click	to go to the n	next step.User click	to go to the prev	iou

The diagram below show 5.0 MANUFACTURER INFORMATION form. User have to complete all fields with (\*).

Medical Device Registration (MDR-20171213-421)		
5.1 Manufacturer Information		Application Detail
1. Name Of Legal Manufacturer :	XOX	VIEW PREVIOUS APPLICATION
2. Address Of Legal Manufacturer :	XOX	1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
3. Post Code/Zin Code -	202	3.0 MEDICAL DEVICE GROUPING
a Post Court ap Court		4.0 CSDT
4. Country :	BELARUS	S.6 MANUFACTURER INFORMATION
5. Upload Quality Management System Certificate		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
( ISO 13485 or Other Quality Management System standard recognised by MDA)	Optoad file     Supported file Type I flat	7.0 CONFORMITY ASSESSMENT
	Index ded Places	8.0 POST-MARKET SURVEILLANCE
	TEST.odf	A X
C Span	×	
Copeta + Res Ball Ficas Soverhele Copeta + Res Ball Ficas Soverhele Condition The RC Condition The RC Construction The RC Construction Construction The RC Construction The RC Construction The RC Construction The RC Construction Construction The RC Construction		
Click Upload file to upload. The file	must be pdf format and next step.User click	size not more than 300 MB.

form.

The diagram below show 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL form. User have to complete all fields with (\*).

PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL	S	Application Detail
lease indicate whether the medical device has obtained Pre-Market Cleara sreign countries	nce / Pre-Market Approval or considered Exempted/Notified/Self-Declared fro	VIEW PREVIOUS APPLICATION
		1.0 ESTABLISHMENT DETAILS
USFDA		2.0 GENERAL INFORMATION
DA		3.0 MEDICAL DEVICE GROUPING
1. US FDA 510(K) / Pre Market Approval / Notification Number:	10.0	4.0 CSDT
	7.1m	5.0 MANUFACTURER INFORMATION
2. Valid from :	01-11-2017	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
Valid To? (Ves/No)	<b>.</b>	7.0 CONFORMITY ASSESSMENT
**Valid To Date Need To Be Set If Choose Yes	• Yes No	8.0 POST-MARKET SURVEILLANCE
3. Valid to :	19-12-2017	]



form.

The diagram below show 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL form. User have to complete all fields with (\*).

Conformity Assessment		Application Detail
onformity Assessment Dont Need To Be Filled If Device Is For Exportation		MEW PREVIOUS APPLICATION
Name of CAB :	TEST CAB	1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
CAB Registration No. :	MDA/CAB-048	3.0 MEDICAL DEVICE GROUPING
		4.0 CSDT
Conformity Assesment Certificate : Valid From	2017-11-29	5.0 MANUFACTURER INFORMATIO
Conformity Assesment Certificate : Valid To	2017-11-30	6.0 PRE-MARKET CLEARANCE/PRE
		7.0 CONFORMITY ASSESSMENT
Please upload the CAB certificate and CAB Report	Lupload file Supported File Type : Pdf	8.0 POST-MARKET SURVEILLANCE
yen: + + + + + + + + + + + + + + + + + + +	Vploaded Files :- TEST.pdf	▲ ×
k Upload file to upload. The file	must be pdf format and siz	e not more than 300

The diagram below show SURVEILLANCE AND VIGILENCE form. User have to complete all fields with (\*).

The second second second second		Application Detail
<ol> <li>History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box)</li> </ol>	<ul><li>○ Yes</li><li>● No</li></ul>	VIEW PREVIOUS APPLICATION 1.0 ESTABLISHMENT DETAILS
		2.0 GENERAL INFORMATION
2. Has the application/registration been rejected/suspended in other countries?	Yes	3.0 MEDICAL DEVICE GROUPING
	() No	4.0 CSDT
	If Yes, why? *	5.0 MANUFACTURER INFORMATION
	Please upload Post-Market surveillance and vigilance report	6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
	Upload file     Supported file Type i Pdf	7.0 CONFORMITY ASSESSMENT
		8.0 POST-MARKET SURVEILLANCE
	Uploaded Files :-	
* ×	TEST.pdf	ь н
Served Andreas Servers Roll Process Served Richards Sciences Roll Process		
Braphen Constitution Data PC Brackey Decements Decements Brackey Decements Brackey Decements Brackey Decements Brackey Decements Brackey Decements Brackey Decements Dece		

The diagram below show 9.0 DECLARATION OF CONFORMITY form. User have to complete all fields with (\*).

Medical Device Registration (MDR-20171213-421)		>	Application Detail
9.1 DECLARATION OF CONFORMITY			4.0 CSDT
Declaration of Conformity shall be prepared in accordance with the form	at in Please upload Declaration of Conformity		5.0 MANUFACTURER INFORMATION
Appendix 3 of 3rd 3chedule Medical Device Regulation 2012 [DOC Template Ms Word ]	Lupload file Supported File Type : Pdf		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
	Uploaded Files :-		7.0 CONFORMITY ASSESSMENT
	TEST.pdf	4 ک	8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
			9.0 DECLARATION OF CONFORMITY
Previous		Next	10.0 ATTESTATION
			4
Instruk-COMM Dropben: (II Cannes Uplaade Construie Doktop Doktop Documents Downloade Marie File name	b c Al Fais Qpen Cancel		
lick	e must be pdf format and s	ize not	more than 300 ME
Iser click	e next step.User click	evious to	o go to the previou
rm			

The diagram below show 10.0 ATTESTATION form. User have to complete all fields with (\*).

Medical Device Registration (MDR-20171116-344)	>	Application Detail
10.1 ATTESTATION		4.0 CSDT
I, the Manufacturer/Authorized Representative of this/these device(s), hereby declare that :		5.0 MANUFACTURER INFORMATION
This product is a medical device according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737)		6.0 PRE-MARKET CLEARANCE/PRE- MARKET APPROVAL
Is all be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and perfort they these medical device(s).	mano	7.0 CONFORMITY ASSESSMENT
Increby attest that the information and attachment provided on this application is/are accurate, correct, complete and current to this date. Understand and acknowledge that it is an offence under Section 76, of Act 737 to make sign or furnish any declaration, or other document with the information of the i		8.0 POST-MARKET SURVEILLANCE AND VIGILENCE
intrue, inaccurate or misleading.		9.0 DECLARATION OF CONFORMITY
Previous     Q PREVIEW &	SUBM	10.0 ATTESTATION
	-	Q PREVIEW & SUBMIT
		<

User have to tick all the checkbox before user can submit application. User click

Q PREVIEW & SUBMIT

to preview before submit application.

MDR Class B,C,D Application
1.0 Establishment Details Click To View More
2.0 General Information Click To View More Status
3.0 Medical Device Grouping Click To View More
4.0 CSDT Click To View More Click to see more details about form
5.0 Manufacturer Information Click To View More Complete
6.0 Pre-Market Clearance/Pre-Market Approval Click To View More Complete
7.0 Conformity Assessment Click To View More *Conformity Assessment Dont Need To Be Filled If Device Is For Exportation Complete
8.0 Post-market Surveillance And Vigilence Click To View More
9.0 Declaration Of Conformity Click To View More Complete
10.0 Attestation Click To View More
Click to submit application



### 4.0 CHANGE OF NOTIFICATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



The diagram below show Application List page. Click Change Notification to re-register application.

=	Medical Devi	ce Registration							
FIU	ER APPLICATION								
Show	ng 1-1 of 1 item.								
No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR- 20171116- 344	NEW REGISTRATION	09-12-2017	MANUFACTURER	DEVICE Y IVD	в	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	Q View S ReRegister PAdvice & Receipt Withdrawal Certificate C Change Notification

The diagram below show Change Notification For Registered Medical Device field after user click [Change Notification] button.

≡	Change Notification For Registered Medical Device
Cate	REDITY TYDE
	CATEGORY 1 CATEGORY 2 CATEGORY 3

1) Category 1, changes of medical devices that affect their safety and performance and require new registration of the medical device.

=	Change Notification For Registered Medical Device
Cale	anny Yuna
Care	ba) illu
	CATEGORY 1
	[SELECT TYPE OF CHUNGES]
	Change to the intended purpose and/or indication of use of a registered medical device;
	Change to the risk classification of a registered medical device;
	Change to software that affect safety and performance of the registered medical device;
	Addition of variant(s) not considered a permissible variant according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD-05 Product Grouping First Edition October 2013;
	Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role; and
	Addition of medical devices with device proprietary names different from the registered devices, into a device listing.
	Unless the devices with different proprietary names qualify to be listed together under one listing based on MDA guidance documents on grouping criteria for medical devices registration.
	Category 1 change of medical devices that affect their safety and performance and require new registration of the medical device. Registration holders are required to apply new registration according to Act 737 and Medical Device Registration 2012.
	PROCEED

Next, user will go Medical Device Registration Application field. Tick on the 'MANUFACTURER' or 'AUTHORISED REPRESENTATIVE' to create new application and click on the button

Next to proceed. User can make one application at one time. 'Next' button will enable after

user tick applications checkbox.



✤ For complete step refer 2.2 FILL IN THE APPLICATION FORMS

2) Category 2, changes that require evaluation and endorsement from the MDA prior to implementation of the changes and before placing the market.

Change Notification For Registered Medical Device	
ategory Type	
CATEGORY 1 CATEGORY 2 CATEGORY 3	
[SELECT TYPE OF CHANGES]	
Change in manufacturing facility, process and quality management s	ystem (QMS)
Changes in design or specifications of a registered medical device	
Changes to materials in a general medical device	
Changes to materials in an in-vitro diagnostic (IVD) medical device	
Changes to labelling of medical devices	
Changes to registered medical devices registration information	

3) Category 3, changes may be implemented immediately upon receipt of the acknowledgment from the Authority.

Change Notification For Registered Medical Device
Category Type
© CATEGORY1 ◎ CATEGORY2 ⑧ CATEGORY3
[SELECT TYPE OF CHANGES]         Change in manufacturing facility, process and quality management system (QMS)         Changes in design or specifications of a registered medical device         Changes to labelling of medical devices         Changes to registered medical devices registration information

#### 5.0 CHANGE OF OWNERSHIP

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Change Of Ownership' to create new form.



The diagram below show Change of Ownership page.

Medical Devi	ice Registration - Change Of G	wnership	
• Search Applic	ation Change Of Ownership		
REGISTRATION	NO:		
*Please Insert F	wll REGISTRATION NO : Example : GA70	39017-1	
Search Applica	ation		
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.

=	Medical	Device Registration - Ch	ange Of Ownership			
	Search A	pplication Change Of Owners!	Np			
	REGISTRA	TION NO :				
	*Please Int Search A	vert Full REGISTRATION NO : Exc	mple : GA7639017-1			
	No	License No	Establishment Name	Action		
	1	GA6489317-22	BAIZURA SYAIFULLAH	Q View 0	Charge Of Ownership	
Medical Device Registration - Change	o Of Ownership			Medical Device Registration - Change Of Ownershi	,	
Section 1 : Medical Device Classif	lation			FORM CHANGE OF OWNERSHIP		
Medical Device Role Red Classificat	dian Delada <mark>Cala</mark> r	West Horn	Complete	Establishment Name	<ul> <li>BRIZURA YORFULLAR</li> </ul>	
Establishment Betails COMPLEXE	ta Note		(any set	Submission B	1 M04-20171121-202	
Section 2 : Determine if the Prod	uct A Medical Devi	10		REMARKS		
Determine If The Product & Hedica	al Device <mark>Class So</mark> W	out Mare	Computer			
Section 3 : General Information				Please Upland - 1. Letter O'Authorization (LOA) 2. Letter Issued By Extablishment License	🛓 Uplead the Na results found.	
Medical Device General Information	Click In View Me	3	Computer	Livit Mila	Record To Groups Of Constraints	
					Processo Ye Change Di Demonship	

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

1 Upload file

The diagram below appear after user click [Change Of Ownership] button. Click

## to upload file. The file must be pdf format and size not more than 300 MB. Next, click

Proceed To Change Of Ownership to submit.

Medical Device Registration - Change Of Ownership	
FORM CHANGE OF OWNERSHIP	
Establishment Name	: BAIZURA SYAIFULLAH
Submission ID	: MDR-20171121-262
REMARKS	Example
Please Upload :- 1. Letter Of Authorization (LOA) 2. Letter Issued By Establishment License Unit MDA	<b>⊥ Upload file</b> No results found.
	Proceed To Change Of Ownership

### 6.0 WITHDRAWAL APPLICATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



Medical Device Authority, Ministry of Health Malaysia

aysia User Manual Front End User - Module Utama MDR Class B,C & D Medical Device Centralised Online Application System (MeDC@St 2.0)

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

=	Medical Devi	ice Registration							
FILT	ER APPLICATION	4							
Showi	ing 1-8 of 8 item	s.							
No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR- 20171120- 358	NEW REGISTRATION	11-12-2017	MANUFACTURER	DEVICE X GMD	в	IN-VITRO DIAGNOSTIC MEDICAL DEVICE (IVD)	APPROVAL	Q View

1 Upload file

The diagram below appear after user click [Withdrawal Application] button. Click

## to upload file. The file must be pdf format and size not more than 300 MB. Next, click

Submit To Withdrawal

to submit.	
------------	--

thdrawal Application - MDR-20171120-356		
Medical Device Registration No	: MDR-20171120-356	
Medical Device Name	: DEVICE C	
Proprietary Name/Brand	: NAME C	
Model	: SYSTEM	
Description Of Medical Device	Example	
Intended Use Of Medical Device	Example	
Upload official letter for medical device registration application withdrawal Please upload official letter for medical device registration application withdrawal. Letter must be prepared with company letterhead	LUpload file	
letterhead		

### 7.0 WITHDRAWAL CERTIFICATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



Medical Device Authority, Ministry of Health Malaysia

aysia User Manual Front End User - Module Utama MDR Class B,C & D Medical Device Centralised Online Application System (MeDC@St 2.0)

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

≡	Medical Devi	ce Registration									
RU	ER APPLICATION	¢									
Showing 1-1 of 1 item.											
No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action		
1	MDR- 20171120- 358	NEW REGISTRATION	11-12-2017	MANUFACTURER	DEVICE X GMD	в	IN-VITRO DIAGNOSTIC MEDICAL DEVICE (IVD)	COMPLETE	Q View C3 ReRegister RAdvice & Receipt Withdrawal Certificate Change Notification		



The diagram below appear after user click [Withdrawal] button. Click click

## upload file. The file must be pdf format and size not more than 300 MB. Next, click

Submit To Withdrawal

to submit.

: MDR-20171120-358	
: DEVICE X GMD	
: NAME XX	
: ND CLUSTER	
Example	
Example	
▲ Upload file No results found.	
	<ul> <li>MDR 20171120-358</li> <li>DEVICE X GMD</li> <li>NAME XX</li> <li>IND CLUSTER</li> </ul> Example