

GUIDE TO APPLICATION FOR PRODUCT REGISTRATION

OF HIGHER RISK MEDICAL DEVICE(S) – CLASS B

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to apply for the registration of higher risk medical devices with the Authority for local commerce.

The online <u>Application (Product Registration for Higher risk medical device)</u> in MEDICS may take an average of 5-10 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, Internet performance, etc. For more information, please refer to https://www.hsa.gov.sg/e-services/medics.

Please note that the time stated above excludes time taken for preparatory work in relation to filing the online form (e.g. scanning documents for file attachments.)

INSTRUCTIONS

In order to use this e-Service in MEDICS, you must have all of the following:

- 1. Personal Access Authentication to log on
 - <u>Corppass</u> (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
 - <u>HSA PIN</u> (HSA Personal Identification Number), password for overseas individual, supplied by HSA
- 2. A CRIS Company Account for MEDICS (Client Registration & Identification Services), an account to enable a local company to gain access to MEDICS. See details at <u>cris@hsa</u>.
- **3.** A Registrant Account that is held by a local company who registers medical devices on behalf of a Product Owner.

In the application, you need to provide the following information:

- 1) Each application is for registration of only one SINGLE medical device, or medical device FAMILY, or medical device SYSTEM or GROUP, or TEST KIT for IVD. Please refer to the following guidance documents for more information:
 - GN-12 Guidance on Grouping of Medical Devices for Product Registration
- 2) The softcopy of the supporting documents must be prepared in the ASEAN CSDT format. Please refer to the following <u>guidance documents</u> for more information:
 - GN-15-R1 Guidance on Medical Device Product Registration
 - GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
 - GN-18 Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostics (IVD) Medical Devices using the ASEAN CSDT

REFERENCES

The information in the following guidance documents is useful for the application.

• GN-12 Guidance on Grouping of Medical Devices for Product Registration



- GN-15 Guidance on Medical Device Product Registration
- GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
- GN-18 Guidance on Preparation of a Product Registration Submission for In Vitro
 Diagnostics (IVD) Medical Devices using the ASEAN CSDT
- GN-13 Guidance on the Risk Classification of General Medical Devices

PAYMENT

Please refer to the following page for information on fee and payment modes: <u>https://www.hsa.gov.sg/medical-devices/fees</u>.



ONLINE APPLICATION FORM

This online Application Form consists of 8 parts (via Applicant Info; Device Info; Priority Review Scheme; Details of Reference Agency; Device Details; Evaluation Route; Dossier & Supporting Documents; and Remarks).

PPLICATION FORM			
Applicant Info Details of Reference Agency Dossier & Supporting Docume	2. <u>Device Info</u> 5. <u>Device Details</u> ent(s) 8. <u>Remarks</u>	3. <u>Priority Review Scheme</u> 6. <u>Evaluation Route</u>	Please refer to Guidelines on th
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APPLICANT INFO Change the following info if ye	ou are applying on behal	f of the applicant.	
Name : *		NRIC/Passport No. : *	
Tel. No. : *		Fax No. : *	
Email : *			
Drafter Assignment			
Drafter type :	Staff O Partner		
Available Company's Drafters :	Select Drafter 🗸		
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		Diabetes	
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		Infectious Dis	seases
Please select the relevant descrip	ption to your device: *		
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For Part 2, 4, 5 and 6, click on "**Add/Edit Info**" to access that section of the on-line form. For Part 3, make relevant selections and click "**Save**" to proceed. For Part 7, click on "**Attach/Remove Document**" to attach relevant supporting documents.

At the end of the application form, there are 3 button options:



Button - Save Draft

Allows the applicant to save the Application Form for retrieval and submission at a later time. A transaction number will be assigned.

The saved Application Form can be retrieved from "My Drafts" in the Workbench@MEDICS.

Button – Confirm

Allows the applicant to confirm the completed Application Form and the company's declaration on the form before submitting it to MDB. To amend any mistake, click on the "<< **Previous**" Button to return to the Application Form. Before the application is submitted, the applicant may print a copy the application for his record.

Button – Close

Closes the application form without saving any changes made.

PART 1 – Applicant Info

I. APPLICANT INFO			
Change the following info if yo	ou are applying on beha	alf of the applicant.	
Name : *		NRIC/Passport No. : *	5
Tel. No. : *		Fax No. : *	
Email : *			
Drafter Assignment			
Drafter type :	Staff O Partner		
Available Company's Drafters :	Select Drafter 🔻		

The applicant refers to the individual designated by the company as contact point for any correspondence regarding this application. This section requires the applicant to fill in the following:

1) Name
 2) NRIC/Passport No
 3) Contact Telephone Number
 4) Contact Fax Number
 5) Contact E-mail

Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

Drafter Assignment

This is to allow designated staff or external partner to prepare the application form as a drafter. Note that the completed application will then need to be submitted by someone authorised as a submitter.

A Submitter is allowed to prepare drafts and submit applications without the help of an intermediary drafter. The role of the current login user is displayed at the top of the screen under the Logon ID.

- 1) Drafter type: The applicant can select either a "Staff" or "Partner"
- 2) Available Company's Drafters: Once the above is selected, the corresponding list of drafters will then be selectable from the drop down list.

The list of available drafter depends on the user setting in the <u>CRIS Management Module</u>. The CRIS Administrator is able to set up company users or service providers/partners to be drafter for this e-Service.



PART 2 – Device Info

APPLICATION FORM			
1. Applicant Info2. Dev4. Details of Reference Agency5. Dev	vice Info 3. Prio ice Details 6. Eva	rity Review Scheme luation Route	Please refer to t
7. Dossier & Supporting Document (s)	narks		Guidelines on the
Fields marked with asterisks * are manda	torv.		
ADD DEVICE INFO			
Device Proprietary/Brand Name : * [Full device name as per label,including oroduct owner name.E.g. if product owner s ABC Pte Ltd and full name as per device abel is XYZ Wound Dressing, please input he Device Proprietary/Brand Name as 'ABC XYZ Wound Dressing")			🧳 Symbol
Description of intended use : * What the product is used for as stated in the Instructions for Use /Operating Manual/ Brochure (if IFU is not available). You may enter a maximum of up to 1000 characters.) in Vitro Diagnostic Device : *	○ Yes ● No		9 1
Standalone Medical Mobile Application : * Standalone Medical Mobile Application refers to a software and/or mobile application that is intended to function by tself and are not intended for use to control or affect the operation of other nardware medical devices.)	🔿 Yes 🖲 No		
Medical Device Class : *	Select Medical Device Class	✓ Classification	
		View Classification Respon	ise

Item 1: Device Proprietary/Brand Name

The applicant is required to provide the name of the device as it appears on the product label.

Item 2: Description of intended use

The applicant is required to provide the intended purpose of the device according to the specifications of the product owner as stated on the product label, instruction of use or promotional materials.

Item 3: In vitro Diagnostic Device

The applicant is required to select whether the device is an *in-vitro* diagnostic device or not.

Item 4: Standalone Medical Mobile Application

The applicant is required to select whether the device is a Standalone Medical Mobile Application.

Standalone Medical Mobile Application refers to a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

Item 5: Selection from a list of classification

The applicant is required to select the device class of the product. Please refer to the following guidance documents for more information:

GN-13-R1 Guidance on the Risk Classification of General Medical Devices

Click on "Add" to add the device after completing all the fields.

To remove a device from the "list of device(s) added", select the corresponding checkbox and click "Remove".

To edit the device info after adding the device to the list, select the corresponding checkbox and click "[Edit]"

Click the "Update Form" Button when all devices are added.

Note:

Only devices of the same class can be added. Risk Class as added here will determine the fields required to be filled in in part 3 below.



PART 3 – Priority Review Scheme

3. Priority Review Scheme	
Please note that applications under Priority Review Scheme w relevant evaluation fees applicable.	ill be reviewed via the Full Evaluation Route with
I would like to opt in for the Priority Review Scheme: *	🕐 Yes 🕐 No
i) Does your application meet the Priority Review qualifying criteria ii)	and iii)? * 🔿 Yes 🙁 No
ii) Please select the relevant healthcare focus area: *	Cancer Diabetes Ophthalmic Diseases Cardiovascular diseases Infectious Diseases
iii) Please select the relevant description to your device: *	
Note: Please be reminded that submission of detailed justification for y requirements.	your selection in (iii) is required as part of documentary
The device represents a breakthrough technology that provides a c marketed technology	linically meaningful advantage over existing legally
	Click Save

Click the "Save" Button when the changes are completed.

Note: If "Yes" was selected to opt in for Priority Review Scheme,

- PART 4 Details of Reference Agency will not be required
- PART 6 Evaluation Route": only "FULL" evaluation route option will be available

PART 4 – Details of Reference Agency

This section requires the applicant to fill in the **Details of Reference Agency** and answer the following questions where applicable:

- 1) Marketed in at least TWO jurisdictions without safety issues for at least 3 years
- 2) Marketed in at least ONE jurisdiction or Singapore without safety issues for at least 3 years
- 3) Was the registration of this medical device rejected by any of the reference agencies or Singapore?
- 4) Was the registration of this medical device withdrawn in any of the reference agencies or Singapore?

APPLICATION FORM				
1. Applicant Info 4. Details of Reference Age 7. Dossier & Supporting Docur (s)	2. Device Info ency 5. Device Details ment 8. Remarks	3. Priority Review Scheme 6. Evaluation Route	<u>Please ref</u> <u>Guidelines</u>	er to the
Details of Reference Agence	-у			
US Food and Drug Adminis	tration (US FDA)			
Japan Ministry of Health, La	abour and Welfare (MHLW)			
European Union (EU)				
Health Canada (HC)				
Australia Therapeutic Good	ls Administration (TGA)			
None of the above				
1. Marketed in at least <u>TWO</u> ju	irisdictions without safety issue	s for at least 3 years :	Yes	
2. Marketed in at least ONE ju	risdiction or Singapore without	safety issues for at least 3 years :	O Yes	
3. Was the registration of this	medical device rejected by ar	y of the reference agencies or Singapore?	O Yes	O No
4. Was the registration of this	medical device withdrawn in a	any of the reference agencies or Singapore?	() Yes	O No

<u>Note</u>: If "**Yes**" was selected for question 3 and/or 4, the following new fields will be displayed to be filled in:

- Reason for rejection and Details for rejection for question 3
- Reason for withdraw and Details for withdraw for question 4



PART 5 – Device Details

This section requires the applicant to fill in the Device Details. Select the device you wish to fill in from the Devices drop-down list

MD0411 - PRE-MARKET APPLICAT	ION FOR MEDICAL DE	VICE > New Application > Edit De	evice Details
APPLICATION FORM			
 <u>Applicant Info</u> <u>Details of Reference Agency</u> <u>Dossier & Supporting Document(s)</u> 	2. <u>Device Info</u> 5. <u>Device Details</u> 8. <u>Remarks</u>	3. <u>Priority Review Scheme</u> 6. <u>Evaluation Route</u>	Please refer to the Guidelines on the
Fields marked with asterisks * are ma	ndatory.		
1. DEVICE LIST			
Please select the Device in the drop-do	wn list below to fill in inforr	mation for that device.	
Devices:	Select Device	•	
	Select Device Up Sample DEV1		

After selecting the devices, the following fields and sub-sections will be displayed:

- 1) Device Proprietary/Brand Name
 - Description of intended use
 - Medical Specialty Area
 - Professional Use Only
 - Biological Material Component
 - Device containing DEHP
 - Device containing latex
 - Custom-made Device
 - Device with measuring function
 - System or Procedure Pack
 - Sterile Medical Device
 - Description of sterile medical device
- 2) Product Owner Info
- 3) Manufacturing Site(s) Info
- 4) Model(s) Info
- 5) Importer & Wholesaler Info

For sections 2, 3 4 and 5, click on "Add/Edit Info" to access the sub-section and fill in the details accordingly.



ID0411 - PRE-MARKET APPLICATIO	N FOR MEDICAL DE	VICE > New Application > Edi	it Device Details
PPLICATION FORM			
Applicant Info 2. Details of Reference Agency 5. Dessier & Supporting Document(s) 8	Device Into Device Details Remarks	 <u>Priority Review Scheme</u> <u>Evaluation Route</u> 	Please refer to t Guidelines on the
ields marked with asterisks * are mandato	ry.		
. DEVICE LIST			
Please select the Device in the drop-down li	st below to fill in informat	tion for that device.	
Devices:	Sample DEV1	~	
Device Proprietary/Brand Name : *	Sample DEV1		🦚 Sym
Full device name as per label,including pro wner name.E.g. if product owner is ABC Pt	duct :		
td and full name as per device label is XYZ Vound Dressing, please input the Device Proprietary/Brand Name as "ABC XYZ Woun Dressing")	d		
Description of intended use : *	Sample Description		
What the product is used for as stated in the	he Sample Description		
Brochure (if IFU is not available). You may	enter		
maximum of up to 1000 characters.)	had to continue 2 Device	7-6-	/
n Vitro Diagnostic Device : *	Yes No	Into.	
tandalone Medical Mobile Application : *	Yes No		
Standalone Medical Mobile Application refe s software and/or mobile application that is ntended to function by itself and are not ntended for use to control or affect the operation of other hardware medical device	rs to		
1edical Device Class : *	CLASS B		\checkmark
Indical Specialty Area + *			
fedical Specialty Area : *	Select Medical S	pecialty Area 🗸	
Professional Use only : A "for professional use only" medical devic medical device that is to be used on an indi solely by, or under the supervision of a qual practitioner.)	O No O Yes e is a vidual lífied		
Biological Material Component : Use 'CTRL' key to select/deselect he item(s))	Select Medical S Human Bovine Ovine	pecialty Area	
Device containing DEHP :	No O Yes		
Device containing latex :	No O Yes		
Custom-made Device :	No O Yes		
Device with measuring function :	No O Yes		
System or Procedure Pack :	No O Yes		
Sterile Medical Device :	No O Yes		
>escription of sterile medical device : (e.g. terilization methods)			
DRADUCT OWNER THEA			11
Please provide product owner info.			
			Click <u>Add/Edit I</u>
MANUFACTURING SITE(s) INFO Please provide manufacturing site(s)	info.		
			Click Add/Edit I
MODEL(s) INFO			Show <u>How Coll 1</u>
Please provide model(s) info.			
Please select one or more of the below U	DI Issuing Agency checkb	oxes if you've entered UDI informat	tion in the Device List
			Click Add/Edit I
. IMPORTER & WHOI FSALER THEO			
	u Tufa		
Please provide Importer & Wholesale	er Info.		
			Click Add/Edit I
To update device, enter the device info	and click Update.		



Product Owner Info:

1. Applicant Info	2. Device Info	3. Product Owner Info	
4. Manufacturing Site(s) Info	5. Model(s) Info	6. Importer & Wholesaler Info	Please refer to th
7. Remarks from MDB	8. Remarks		Guidelines on the
Fields marked with asterisks * an	e mandatory.		
Fields marked with asterisks * an PRODUCT OWNER INFO	e mandatory.		
Fields marked with asterisks * an PRODUCT OWNER INFO	e mandatory.		
Fields marked with asterisks * an PRODUCT OWNER INFO Product Owner Name :	e mandatory.	wner 💙 Cl	ick <u>Populate</u>

- Select a Product Owner from the drop-down list
- Click "Populate" to select it

Product Owner Name :	Click Populate
To add a new Product Owner p Add New.	articulars in below section if it does not exist in the selection list, click on
Product Owner Info	
Company Name : *	ME Refue To co
Address Type : *	100
Postal Code : *	
Block/No. :	
Street Name :	
Building Name :	AND DESIGN OF ANY
Level - Unit :	
Country : *	CONTRACTOR CONTRACTOR
Main Tel. No : *	MARKET MARKET AND ADDRESS
Contact Person : *	b. Sand
Contact Tel. No. : *	
Contact Email : *	
	(For future communication and email notification.)

- Modify the contact details if necessary

<u>Note</u>: if your product owner is not in the drop-down list, click on "**Add New**" to manually add and select the newly added product owner.



Manufacturing Site(s) Info:

APPLICATION FOR	۲M	
1. Manufacturing	Site(s) Info 2. Add/Update Manufacturing Site	Please refer to th Guidelines on the.
Fields marked with	asterisks * are mandatory. STIE(s) INFO	
Fields marked with MANUFACTURING Site Location :	asterisks * are mandatory. SITE(s) INFO © Local © Overseas	
Fields marked with MANUFACTURING Site Location : Site Name :	asterisks * are mandatory. SITE(s) INFO CLocal O Overseas Starts With	Click <u>Search</u>

- Use the search function to search for existing manufacturing site(s) -
- Select the manufacturing site(s) from the result list Click "**Add**" to add the selected site(s) -
- -
- To remove, select the site(s) from the List of Manufacturing Site(s) selected, then click "Remove" -

ite Na	ma		0 1000		1013003			-		1/20		
nice into	ine .	_	S						Contains	•		Click Search
ist of	Man	ufacturing	Site(s)									
otal /	recor	o'n N				Page		of 1 Go	[[firs	t] [P	revious	[next] [last]
5/NO.		Site Name							Quality Sy	stem/	Expiry D	ate
o sel o ado	ect a l a ne	manufacti ew manufa	uring site	e, sele iite, cli	ct the checkt ick <u>Add New :</u>	oox and clie <u>Site</u> .	ck <u>Add</u>	•				
/No.		Site Name	Site(s)	electe	d				Quality Sy	stem/	Expiry Da	ate
•					-							
lick o	n the	Manufacturi a manufac	ng site na turing s	me to c ite froi	complete the Q m the above	uality syster list, select	m/Expir the ch	y Date infi eckbox a	ormation.	Remo	ve.	

Note: if your manufacturing site does not exist, click on "Add New Site" to manually add and select the newly added manufacturing site.



Model(s) Info:

PPLICATION FORM			
. Applicant Info . Manufacturing Site(s) Info . Remarks from MDB	2. Device Info 5. Model(s) Info 8. Remarks	3. Product Owner Info 6. Importer & Wholesaler Info	<u>Please refer to the</u> <u>Guidelines on the.</u>
MODEL(5) INFO			
To add multiple model inf) (Click <u>here</u> (Right click & Save	e Target As) to download the excel template) :	
Manufacturing Site(s) List Site ID Site Name	site Address		
and the second second second			
Note: Please input the Site II	D at the excel file as shown abo	ve for the upload.	
Choose File No file cho	sen		
Append to Existing Model I	ist OClear Existing Model List		
Upload			
Model Name			
Model Number			
UDI-DI 🕐			
UDI-DI ? DM-DI (Only if DM-DI is available and is different fror UDI-DI) ?	n		
UDI-DI [?] DM-DI (Only if DM-DI is available and is different fror UDI-DI) [?] Description (e.g. Clinical Size (including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UD DJ)) (Max 3000 Characters)			
UDI-DI [?] DM-DI (Only if DM-DI is available and is different fror UDI-DI) [?] Description (e.g. Clinical Size (including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UD DI) (Max 3000 Characters) Manufacturing Site(s)	n		
UDI-DI [2] DM-DI (Only if DM-DI is available and is different fror UDI-DI) [2] Description (e.g. Clinical Size (including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UD DI)) (Max 3000 Characters) Manufacturing Site(s) Site Name (Postal Code) [Sit ID]	n		

- You can either download and fill in the Excel template to upload the Model list via the "**Upload**" function OR
- Manually fill in the following fields and "Add to List" the Model one by one
 - Model Name
 - Model Number
 - o UDI-DI
 - o DM-DI
 - Description
 - Manufacturing Site(s)
- To remove, select the model(s) from the Model(s) Added list, then click "Remove"

5/No.	Delete? Model Name	Model Number	UDI-DI	DM-DI	Description (Max 3000 Characters)	Manufacturing Site(s)
1.	Model 01	Mo01	udi1,udi2,udi3	dm1,dm2,dm3	Model 01	And the second second
To rei	nove a model from at	ove list : Select the	e checkbox and c	ick Remo	ve button.	

- After populating the fields, click "Update Form" to save the Device Details.
- Select the UDI Issuing Agency.

Please provide model(s) info.	
Please select one or more of the below UDI Issuing Agency checkboxes if you've en GS1 HIBCC ICCBRA	tered UDI information in the Device List
1. Model 01 (Model # : Mo01), (UDI: udi1,udi2,udi3), (DM: dm1,dm2,dm3), Mode	el 01



Importer & Wholesaler Info:

			Please refer to t
1. Applicant Info 4. Manufacturing Site(c) Info	2. Device Into 5. Model(c) Info	3. Product Owner Info 6. Importer & Wholesaler Info	Cuidelines on the
Pemarks from MDB	8 Remarks	o, importer a wholesaler into	Guidelines on the
ossier No.: -			
ossier No.: - fields marked with asterisks =	are mandatory.		
Dossier No.: - Fields marked with asterisks * mporter & Wholesaler Info	are mandatory.		

- Use the search function to search for existing Importer(s) and Wholesaler(s)
- Select the Importer(s) and/or Wholesaler(s) from the result list
- Click "Add" to add the selected site(s)
- To remove, select the site(s) from the List of Licence(s) selected, then click "Remove" Fields marked with asterisks * are mandatory.

Licent	e Name	S	Contains -	Click Search
List c	flicence	e(s)		
S/No	1	Joence Name		Licence Type
1				Importer
2				Importer
3				Importer
4	8			Importer
5				Wholesaler
To se	lect a lie	cence : Select the checkbox and click Add		
List o	f Licenc	es(s) selected		
S/No.		Licence Name	Licence Type	
1		MEDICS TEST COMPANY 1 [ES0500277]	Wholesaler	
2		MEDICS TEST COMPANY 1 [ES0500331]	Importer	
To re	move lie	cence(s) from the above list, select the check	box and click Remove	

After filling all mandatory fields and sub-sections, click "Update Form" to save the Device Details.

Note:

- If there are multiple devices under the same draft, use the drop-down list at the top to switch between devices.
- After filling in the first device, switching to a new device will trigger the auto-copy function where all fields except the Model(s) Info are copied over for your convenience.

PART 6 – Evaluation Route

This section requires the applicant to select the Evaluation Route from the available options according to inputs in the previous completed sections.

6. EVALUATION ROUTE							
Evaluation Route :	Select Evaluation Route						
	Full						
Route Definition:	Abridged						
	IBR						
Immediate B Registration (IB							
Approval by 1 of HSA's independe	ent reference agencies and mar	keted in at least ONE jurisdiction or Singapore without					
safety issues for at least 3 years.	safety issues for at least 3 years.						
OR							
Approval by 2 of HSA's independe	ent reference agencies.						
OR							
Standalone Medical Mobile Applica	ation with approval by at least 1	of HSA's independent reference agencies.					
Terreradiate C. Basisteration (TC	n).						
Standalone Medical Mehile Applie	K): ation with approval by at least 1	of HCA's independent reference paperios					
Standalone Medical Mobile Applica	ation with approval by at least 1	or HSA's independent reference agencies					
Expedited C Registration (ECE	2).						
ECR 1: Approval by 1 of HSA's i	independent reference agencies	and marketed in Singapore and any market without safety					
concerns for at least 3 years.		and marketed in bingapore and any market menode safety					
ECR 2: Approval by 2 of HSA's i	independent reference agencies						
,,, _,, _							
Expedited D Registration (ED	R): Approval by 2 of HSA's inde	pendent reference agencies.					
. ,		-					
Note: EU and TGA are counted as	1 reference agency.						



PART 7 – Dossier & Supporting Document(s)

This section requires the applicant to upload supporting documents for each device.

The supporting document in ASEAN CSDT format can be attached under "Other document" in this section of the application.

The supporting documents are attached by:

DC	SSIER & SUPP	DRTING DOCUMENT(s)			
Ple an	ease refer to the did IVD category	ne Guidelines on the documents t y for Pre-Market Application.	o be attached for diffe	erent category of Me	dical Device classes
1.	All	Letter of authorization *	path of click on the brow	se button.	Browse
	Sample DEV 1				

attaching these documents by clicking on the "Add Attachment" after all documents have been selected

All Sample DEV 1	Manufacturing Information (site's name and address) *	Browse)

To attach, click Add Attachment.

To remove documents from the "list of documents attached", select the corresponding checkbox and click "Remove Attachment".

S/No.	8	Device Name	Document Name	Description	Size (KB)	Uploaded Date
1.	Π	Sample DEV 1	Notes.txt	Letter of authorization	1	04/01/2013

Click the "Update Form" Button when all required documents are attached.

Note:

- If a document is applicable for more than one device, you can select multiple devices from the selection box before browsing to the document and uploading it.
- If a document is applicable for ALL devices, you can select All from the selection box before browsing to the document and uploading it.
- If the device name is too long and you cannot distinguish them due to the limit of the section box, move the mouse over to the device name, the full name will be displayed below the mouse cursor.

PART 8 – Remarks

This section is for the applicant to insert any remarks to MDB regarding the application.

8. REMARKS		
Remarks to MDB : (You may enter a maximum of up to 1000 characters.)	^	
	~	

END OF DOCUMENT