GUIDE TO SUBMISSION OF UPDATE TO CLASS A MEDICAL DEVICE EXEMPTION LIST

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows an Importer or Manufacturer to update the Class A Medical Device Exemption List.

The online Submission of Update to Class A Medical Device Exemption List 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**
    - Corppass (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
    - HSA PIN (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 cris@hsa.

3. **An active Importer or Manufacturer Licence.**

PAYMENT

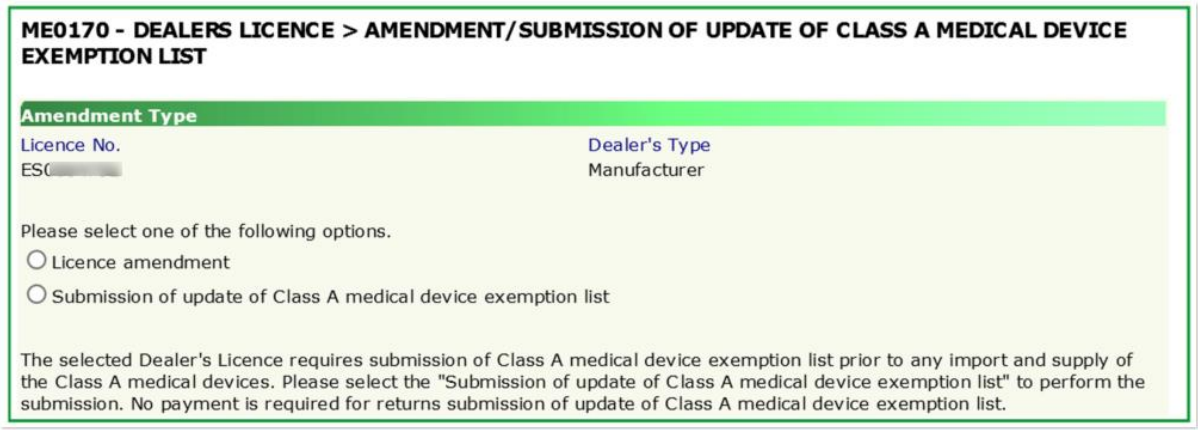
No fee is applicable for this application.

SEARCH SCREEN

This search screen allows you to search for dealer's licence (manufacturer or importer licence) under your company. Eligible dealer's licence will be listed under the search result.

Select **"Dealer's Licence"** from the Licence/Registration Type drop-down list and click **"Search"** to retrieve the dealer's licence accordingly.

After retrieving the dealer's licence (manufacturer or importer licence), click on the appropriate licence no. to proceed.

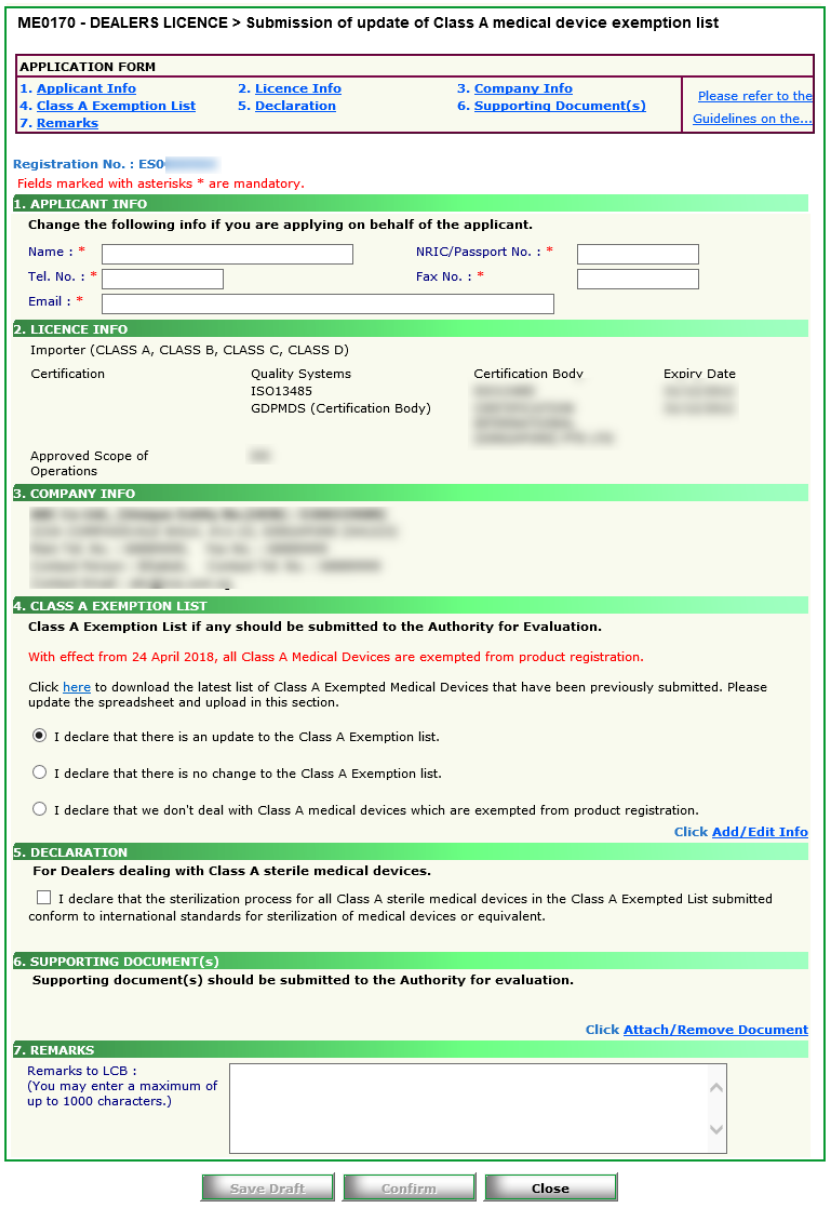


Select "**Submission of update of Class A medical device exemption list"** and click "**Next**" to proceed to the online application form.

ONLINE APPLICATION FORM

The online application form consists of 7 parts.

To make an amendment, click on **"Add/Edit Info"** to access that section of the form



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 make any amendments, click on the **"<< Previous"** Button to return to the Application Form. Before the application is submitted, the applicant may print a copy of the application for his record.

Button – Close
Closes the application form without saving any changes made.

PART 1 – Applicant Info

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.

PART 2 – Licence Info

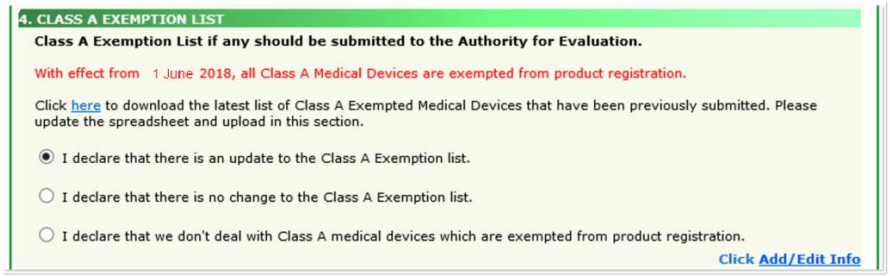
This section is read-only.

PART 3 – Company Info

This section is read-only.

The details in this section can only be changed via MEDICS E-service, Change@medics, "Change of Business Information".

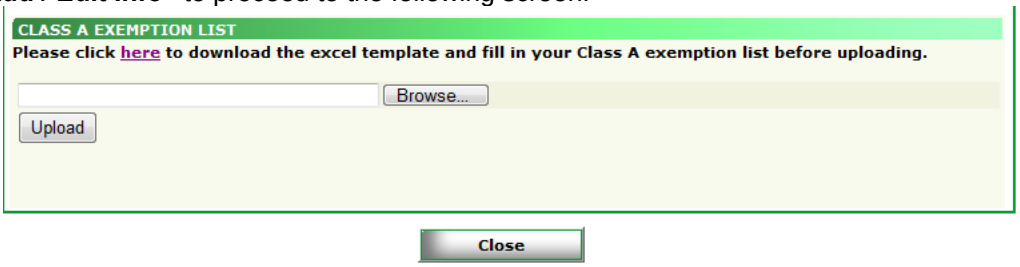
PART 4 – Class A Exemption List



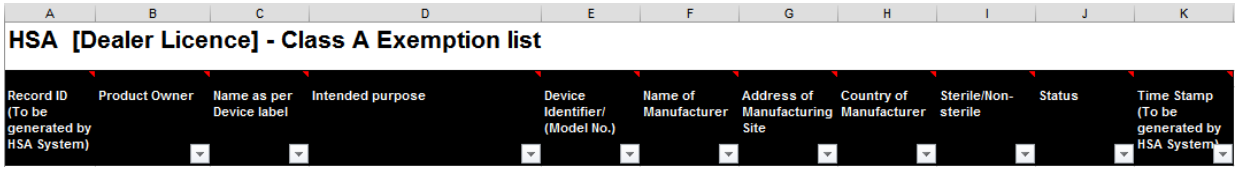
1) If there is no change to the Class A Exemption List, select "**I declare that there is no change to the Class A Exemption list**".
2) If company does not deal with Class A exempted medical devices, select "**I declare that we don't deal with Class A medical devices which are exempted from product registration**".
3) To update the Class A Exemption List, select "**I declare that there is an update to the Class A Exemption list**".

If the Class A exemption list was previously submitted, click "**here**" link to download and save the latest list.

Click "**Add / Edit Info"** to proceed to the following screen.



If Class A Exemption list was never submitted, click "**here**" link to download the empty excel template to fill up the required information for Class A Exemption list.



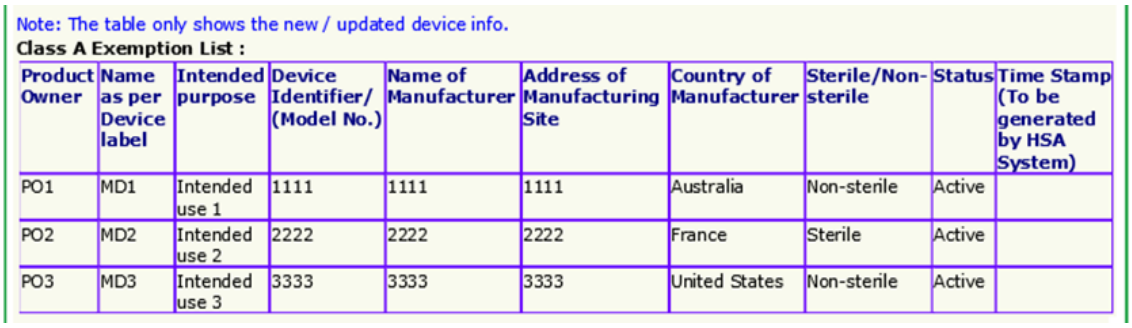
A	B	C	D	E	F	G	H	I	J	K
HSA [Dealer Licence] - Class A Exemption list										
Record ID (To be generated by HSA System)	Product Owner	Name as per Device label	Intended purpose	Device Identifier/ (Model No.)	Name of Manufacturer	Address of Manufacturing Site	Country of Manufacturer	Sterile/Non-sterile	Status	Time Stamp (To be generated by HSA System)

Note

1. The excel file cannot contain any blank cells within the columns B – columns J and should not have any blank rows in between, in order to be uploaded successfully.
2. No input from the applicant is required for the first column (Record ID) and the last column (Time Stamp).
3. Any new / updated Class A Exempted Medical Devices uploaded in the application will be appended to the previous list upon clicking <Update Form> button if the device does not come with the Record ID.
4. If an item on the list has been "rejected" by HSA, the applicant is not allowed to update the "rejected" status to "Active" / "Inactive".

After completing the Class A Exemption list, click "**Browse**" to select the excel file and click "**Upload**".

Once the excel file is successfully uploaded, a table on the declared Class A medical devices exempted from product registration will be displayed.



Note: The table only shows the new / updated device info.

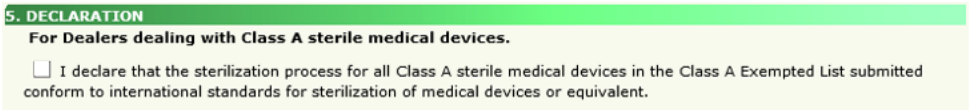
Class A Exemption List :

Product Owner	Name as per Device label	Intended purpose	Device Identifier/ (Model No.)	Name of Manufacturer	Address of Manufacturing Site	Country of Manufacturer	Sterile/Non-sterile	Status	Time Stamp (To be generated by HSA System)
PO1	MD1	Intended use 1	1111	1111	1111	Australia	Non-sterile	Active	
PO2	MD2	Intended use 2	2222	2222	2222	France	Sterile	Active	
PO3	MD3	Intended use 3	3333	3333	3333	United States	Non-sterile	Active	

Click "**Update Form**" to proceed.

PART 5 – Declaration

Checkbox "**I declare that the sterilization process for all Class A sterile medical devices in this Class A Exempted List submitted conform to international standards for sterilization of medical devices or equivalent**" will be enabled if there is/are Class A sterile medical devices in the Class A Exemption List uploaded. Checkbox has to be selected in order to proceed with the submission.



5. DECLARATION

For Dealers dealing with Class A sterile medical devices.

☐ I declare that the sterilization process for all Class A sterile medical devices in the Class A Exempted List submitted conform to international standards for sterilization of medical devices or equivalent.

Checkbox will be disabled if all entries have been changed to inactive.

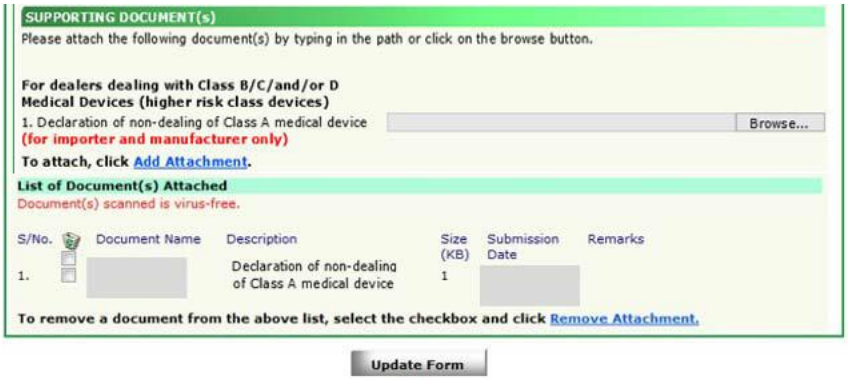
PART 6 – Supporting Documents

The supporting documents are attached by browsing the local storage devices for the documents using the **"Browse"** button. Then click the **"Add Attachment"** button to attach these documents.

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

Click **"Update Form"** when all required documents are attached.

"***Annex 6: Declaration of Non-Dealing of Class A medical device***" of GN-02 is mandatory if companies are not dealing in Class A medical devices which are exempted from registration.



PART 7 – Remarks

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

END OF DOCUMENT