

GUIDE TO PRE-MARKET CONSULTATION SCHEME APPOINTMENT BOOKING SYSTEM

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 AppointmentBooking@medics in MEDICS may take an average of 5-10 minutes to fill in.

The time taken varies depending on the number of appointments to be made, configurations of your computer and network system, Internet performance, etc. The recommended computer and network configurations are at http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/System_Requirement_for_accessing_MEDICS.html.

INSTRUCTIONS & REFERENCES

For detailed information on the different Pre-Market Consultations, please refer to the following URL:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates.html

PAYMENT

The only mode of payment accepted for Pre-Market Consultation Scheme Appointment Booking is via Online Payment (VISA, Mastercard).

It is advisable to print the online acknowledgement of payment and receipt for your own records.


ONLINE APPOINTMENT BOOKING FORM

Access the AppointmentBooking@medics e-Service from HSA website. After logging in and accepting terms and conditions, the following screen will be displayed. Enter the 'Captcha' code for security check and click on "Next" button once you have done.

AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

Booking Authorisation

Security Check:
Can't read the word below? [Try different words](#)



Please enter the word you see above:

PART 1 – Applicant Info

This is the individual, or person designated by the company, who will be the contact point for any correspondence regarding this appointment.

Please ensure that the information entered is accurate to ensure prompt receipt of any email correspondence from HSA regarding this appointment

The invoice and receipt for the fees paid will be billed according to the billing address entered under this part.

Click on "Next" button once you have completed this section.

AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

Transaction No: TMD175071121

APPLICATION FORM

[1. Applicant Info](#) [3. Confirmation](#)
[2. Booking Info](#)

Fields marked with asterisks * are mandatory.

1. APPLICANT INFO

1.1 Name: *	<input type="text" value="CFE APP BOOKING APPLICANT"/>
1.2 Email: *	<input type="text" value="cfe@cfe.com"/>
1.3 Contact Number: *	<input type="text" value="91111111"/>
1.4 Company Name (Optional):	<input type="text" value="CFE PTE LTD"/>
1.5 Address Type: *	<input checked="" type="radio"/> Local <input type="radio"/> Overseas
1.6 Postal Code: *	<input type="text" value="560648"/> Retrieve Billing Address
1.7 Block / House No.: *	<input type="text" value="648"/>
1.8 Street Name: *	<input type="text" value="ANG MO KIO AVENUE 5"/>
1.9 Building Name:	<input type="text" value="ANG MO KIO 61"/>
1.10 Level - Unit:	# <input type="text"/> - <input type="text"/>
1.11 Country:	SINGAPORE

PART 2 – Booking Info

This section requires the applicant to select the consultation type and appointment slots.

AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

Transaction No: TMD17507269J

APPLICATION FORM

1. Applicant Info 3. Confirmation
2. Booking Info

Fields marked with asterisks * are mandatory.

2. BOOKING INFO

2.1 Consultation Type: * Device Development
 Device Pre-Submission

DEVICE DEVELOPMENT CONSULTATION
 Device Development Consultation is to allow medical device developers and/or researchers to seek regulatory advice during various stages of medical device development in preparation for regulatory submission. Stakeholders may seek input on device validation plans, clinical studies or other aspects relating to local medical device regulations. This consultation is not an endorsement to any validation plans, test protocols and results discussed. The consultation is not meant to be an iterative process and does not guarantee approval or clearance for pre-market registration.

DEVICE PRE-SUBMISSION CONSULTATION
 Device Pre-submission Consultation is to allow companies to seek feedback on their device dossier prior to pre-market submission. The purpose of this consultation is to assess the completeness of the submission dossier in accordance with the prescribed Common Submission Dossier Template (CSDT) format, per GN-17 or GN-18, and appropriateness of the supporting documents. This pre-submission consultation is not a scientific evaluation of the medical device. The consultation is not meant to be an iterative process and does not guarantee approval or clearance for pre-market registration.

2.2 Device Type: * General Medical Device
 In-Vitro Diagnostic

2.3 Appointment Date (dd/mm/yyyy) : *

2.4 Appointment Time: *

S/No.	Consultation Type	Device Type	Appointment Date	Appointment Time
<input type="checkbox"/> 1	Device Development	General Medical Device	25/08/2017	14:00

Item 1: Consultation Type

Applicant is required to select the consultation type. A brief description of the different consultation type is provided in the application form. Further information is available at the following URL:

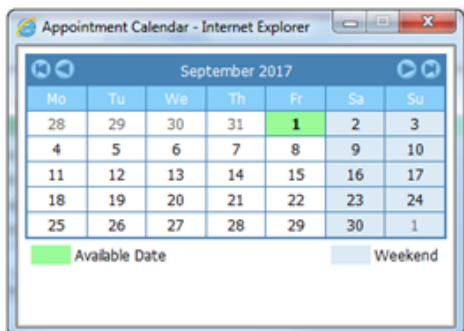
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Medical%20Device%20Pre-Market%20Consultation%20and%20Priority%20Review%20Scheme.pdf

Item 2: Device Type

Applicant is required to select the type of device, General Medical Device or In-Vitro Diagnostic Device, to be consulted on during the session.

Item 3: Appointment Date

Applicant may click on the calendar icon to browse for dates that are available for booking.



Item 4: Appointment Time

Upon selection of the preferred date in Item 3, available time slots for the selected day will be displayed in this section. Applicant is required to click on the drop-down menu and select the preferred timeslot.

Click "Add" to add the selected timeslot.

Applicant may add more than 1 appointments in the application.

Click on "Next" button once you have done with the selection of desired timeslots.

PART 3 – Confirmation

The system will display all the information that was entered in Part 1 and Part 2. Applicant is to review and ensure that the information is accurate before submission.

AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

Transaction No: TMD17507112I

APPLICATION FORM

1. Applicant Info	3. Confirmation
2. Booking Info	

*Fields marked with asterisks * are mandatory.*

3. CONFIRMATION

3.1 Name: * CFE APP BOOKING APPLICANT
 3.2 Email: * cfe@cfe.com
 3.3 Contact Number: 91111111
 3.4 Company Name(Optional): CFE PTE LTD
 3.5 Address Type : * Local
 3.6 Postal Code : * 560648
 3.7 Block / House No. : * 648
 3.8 Street Name : * ANG MO KIO AVENUE 5
 3.9 Building Name : ANG MO KIO 61
 3.10 Level - Unit : # -
 3.11 Country : SINGAPORE

SN	Consultation Type	Device Type	Appointment Date	Appointment Time
1	Device Development	General Medical Device	25/08/2017	13:00
2	Device Development	In-Vitro Diagnostic	31/08/2017	15:00

Click on “Submit” button to confirm the information and system will redirect applicant to payment advice page. Click on “Back” button to go back Section 2 for any amendment on the information.

Please note that bookings are not confirmed until payment is completed.

Payment Advice

PAYMENT ADVICE

Please indicate your payment mode and click Submit button to confirm payment. If you do not wish to proceed with payment, click on the Cancel button.

Transaction Type : NEW - Date/Time : 11/07/2017 17:20
Payment Mode :
Payment Method : Credit Debit

Important Notice for eNETS Debit payment:
Please take note to turn off the pop-up blocker in your browser before proceeding to submit your application in-order to view the Acknowledgement and Receipt.

Client Code : C1788888Z
Transaction No. : TMD17507112I
Progressive Payment : Full Payment Progressive Payment

S/No.	Description	Unit Price (S\$)	Qty	Amount (S\$)
1.	BR17503965H MD Development Consultation Fee	500.00	1	500.00
2.	BR17503966I MD Pre-Submission Consultation Fee	200.00	1	200.00
Total (S\$):				700.00

This is a computer-generated payment advice. No signature is required.

The Evaluation Fee displayed above (if any) will be billed to you after the application is accepted for evaluation. Please print a copy of this advice for reference.

1. For GIRO company, the payment will be deducted from your bank account.
2. For on-line payment (e.g. credit card) you will be directed to the Government payment gateway.
3. Please note that cash collection over the counter is discontinued on and after 1 April 2005.
4. Please note that cheques payment has been discontinued.

Payment advice page will be display the total amount to pay for the Pre-Market Consultation appointment booking.

Click on "Submit" to proceed to make payment according to submit the application.

Click on "Cancel" to return to the draft Pre-Market Consultation Appointment Booking application.

Please note that bookings are not confirmed until payment is completed.

ONLINE APPOINTMENT INQUIRY FORM

DRAFT BOOKINGS

Applicants will be able to retrieve the draft Pre-Market Consultation Appointment Booking through the CFEAppointmentInquiry@medics by searching with the following information that was previously entered:

- Email
- contact number
- Booking Reference No.

By click on the hyperlink of the Transaction No, applicant can edit and proceed with submission of the draft application

AB1002 Appointment Inquiry for Medical Devices Pre-Market Consultation

Please fill in at least one field marked with asterisks *.

APPOINTMENT BOOKING INQUIRY

Email: *

Contact Number: *

Booking Reference No: *

Total 2 record(s) found. Page 1 Of 1 Page(s)

S/No.	Name	Booking Reference No/Transaction No:	Appointment Slot	Appointment Status
1	CFE APP BOOKING APPLICANT	TMD17507112I	25/08/2017 13:00	Draft
2	CFE APP BOOKING APPLICANT	TMD17507112I	30/08/2017 16:00	Draft

Total 2 record(s) found. Page 1 Of 1 Page(s)

CONFIRMED BOOKINGS

Applicant able to retrieve and view the information of the confirmed CFE Appointment Booking application through the CFEAppointmentInquiry@medics by searching with the following information that was previously entered:

- Email
- contact number
- Booking Reference No.

No amendments are allowed to confirmed bookings.

AB1002 Appointment Inquiry for Medical Devices Pre-Market Consultation

Please fill in at least one field marked with asterisks *.

APPOINTMENT BOOKING INQUIRY

Email: *

Contact Number: *

Booking Reference No: *

Total 2 record(s) found. Page 1 Of 1 Page(s)

S/No.	Name	Booking Reference No/Transaction No:	Appointment Slot	Appointment Status
1	CFE APP BOOKING APPLICANT	BR17503973P	25/08/2017 13:00	Confirmed
2	CFE APP BOOKING APPLICANT	BR17503974Q	30/08/2017 16:00	Confirmed

Total 2 record(s) found. Page 1 Of 1 Page(s)