




# MeDC@St Hands-On Training for Establishment Licensing

Establishment Unit  
Medical Device Authority


## DASHBOARD

HIDE

 Announcement



## ESTABLISHMENT LICENSING

HIDE

 Application Form



## MEDICAL DEVICE REGISTRATION

HIDE

 New Application Form Application Status




## IN-VITRO DEVICE REGISTRATION

HIDE





 New Application Form IVD Application Status

## ADMIN

HIDE

 Change Password Users Management Logout

Note: \* is compulsory field







ESTABLISHMENT DETAILS		SUPPORTING DOCUMENTS
TYPE OF ESTABLISHMENT*	<input type="checkbox"/> MANUFACTURER	 <a href="#">UPLOAD</a>
	<input type="checkbox"/> AUTHORISED REPRESENTATIVE	Authorization letter template can be downloaded below: 1. <a href="#">Authorized Representative</a>
	<input type="checkbox"/> DISTRIBUTOR	 <a href="#">UPLOAD</a>
	<input type="checkbox"/> IMPORTER	Authorization letter template can be downloaded below: 2. <a href="#">Distributor</a>
BUSINESS REG. NO.*	123 - SS	 <a href="#">UPLOAD</a>
ESTABLISHMENT NAME*	ARAIZ	 <a href="#">UPLOAD</a>
ADDRESS*	<input type="text"/> <input type="text"/> <input type="text"/>	
POSTCODE*	<input type="text"/>	
STATE*	[ Select ] ▼	
TELEPHONE*	<input type="text"/>	
FAX*	<input type="text"/>	
COMPANY WEBSITE	<input type="text"/>	

# APPLICATION FORM

## Section: Establishment Details

ESTABLISHMENT LICENCE APPLICATION FORM (FORM ID: E288-20130708-523)

Note: \* is compulsory field

ESTABLISHMENT DETAILS		SUPPORTING DOCUMENTS
TYPE OF ESTABLISHMENT*	<input type="checkbox"/> MANUFACTURER <input type="checkbox"/> AUTHORISED REPRESENTATIVE <input checked="" type="checkbox"/> DISTRIBUTOR <input checked="" type="checkbox"/> IMPORTER	 <a href="#">UPLOAD</a> Authorization letter template can be downloaded below: 1. <a href="#">Authorized Representative</a>  <a href="#">UPLOAD</a> Authorization letter template can be downloaded below: 2. <a href="#">Distributor</a>  <a href="#">UPLOAD</a> Authorization letter template can be downloaded below: 3. <a href="#">Importer</a>
BUSINESS REG. NO.*	666666 - A	
ESTABLISHMENT NAME*	BBBBBB	 <a href="#">UPLOAD</a>  <a href="#">Borang Bay...pdf</a>  <a href="#">Borang Per...pdf</a>
ADDRESS*	<input type="text"/> <input type="text"/> <input type="text"/>	
POSTCODE*	<input type="text"/>	
STATE*	[ Select ] ▼	
TELEPHONE*	<input type="text"/>	
FAX*	<input type="text"/>	
COMPANY WEBSITE	<input type="text"/>	

## Tool-tips for Establishment Licence Online Application

ESTABLISHMENT DETAILS		SUPPORTING DOCUMENT
Type of Establishment	Please tick the appropriate box/boxes.	<ul style="list-style-type: none"> <li>• Authorisation letter template               <ol style="list-style-type: none"> <li>1. Authorised Representative</li> <li>2. Distributor</li> <li>3. Importer</li> </ol> </li> </ul>
Business Reg. No	As appeared in the Registrar of Companies Malaysia Certificate (ROC).	
Establishment Name	Name of the establishment as appeared in the ROC.	<ul style="list-style-type: none"> <li>• Copy of ROC</li> </ul>
Address	Please fill full address AT LEAST 2 ROW of the establishment.	
Postcode	Example: 62300	
State	Please select the state.	
Telephone	Example: 603xxxxxxx	
Fax	Example: 603xxxxxxx	
Company Website	Company website in Malaysia.	

# Template for Letter of Authorisation for AR

## Template for Letter of Authorisation for Authorised Representative

*[To be printed on Company Letterhead of the foreign manufacturer who is the brand owner of the medical device to be registered]*

Medical Device Authority

Malaysia

*[Date]*

Dear Sir/Madam,

**Subject:** Letter of Authorisation for *[name of Authorised Representative]*

We, *[name of the foreign manufacturer]*, as the manufacturer of the medical device listed in Attachment 1, hereby authorise *[Company name (Registration Number) or Person name (IC Number) and address]*, as the Authorised Representative to prepare and submit applications for the evaluation and registration of medical devices to the Medical Devices Authority on our behalf.

We also authorise *[name of Authorised Representative]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Medical Device Act 2012 (Act 737), the Medical Device Regulation 2012 and any other applicable laws that may also be in force.

This authorisation shall remain in effect until our notification to the Medical Device Authority in writing (either by postal mail, e-mail or facsimile transmission) that the authorisation is revoked subject to any conditions imposed by the Authority.

We undertake to provide all the necessary support and assistance to the Authorised Representative as may be required in relation to any matter involving the medical devices listed in Attachment 1.





We acknowledge that any non-compliance with any registration condition issued by the Medical Device Authority in relation to medical devices registered under Act 737 may result in the suspension or cancellation of the medical device registration.

We agree to furnish and assist the Medical Device Authority with any request for information on the above medical devices.

Yours Sincerely,

# APPLICATION FORM

## Section: Person Responsible



PERSON RESPONSIBLE FOR ESTABLISHMENT		SUPPORTING DOCUMENTS
NATIONALITY*	<input type="radio"/> MALAYSIAN <input type="radio"/> NON-MALAYSIAN <input checked="" type="radio"/> PERMANENT RESIDENT	
NRIC	<input type="text"/>	 <a href="#">UPLOAD</a>
FULL NAME*	<input type="text"/>	
PLACE OF BIRTH*	[ Select ] 	
DATE OF BIRTH*	<input type="text" value="0000-00-00"/>	
DESIGNATION*	<input type="text"/>	 <a href="#">UPLOAD</a>
CORRESPONDENCE ADDRESS*	<input type="text"/> <input type="text"/> <input type="text"/>	
POSTCODE*	<input type="text"/>	
STATE*	[ Select ] 	
TELEPHONE*	<input type="text"/>	
FAX*	<input type="text"/>	
EMAIL*	<input type="text"/>	

## Tool-tips for Establishment Licence Online Application

PERSON RESPONSIBLE FOR ESTABLISHMENT		SUPPORTING DOCUMENT
Nationality	Please tick one box only.	
NRIC/ Passport & Permit	As appeared in the card/passport/permit.	<ul style="list-style-type: none"> <li>• Copy of NRIC/ Passport/ Work Permit</li> </ul>
Full Name	As appeared in an identification document.	
Place of Birth	Name of the province, territory or country.	
Date of Birth	Year-Month-Date	
Designation	Nomination or appointment in the establishment.	<ul style="list-style-type: none"> <li>• Form 49</li> <li>• Letter of Appointment</li> </ul>
Correspondence Address	Address for communication by the exchange of letters for person responsible.	
Postcode	Example: 62300	
State	Please select the state.	
Telephone	Example: 603xxxxxxx	
Fax	Example: 603xxxxxxx	
Email	Email address of the person responsible (Not establishment email)	

# APPLICATION FORM

## Section: Contact Person Details





CONTACT PERSON DETAILS		SUPPORTING DOCUMENTS
<input type="checkbox"/> SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT		
NATIONALITY*	<input checked="" type="radio"/> MALAYSIAN <input type="radio"/> NON-MALAYSIAN <input type="radio"/> PERMANENT RESIDENT	
NRIC	<input type="text"/>	 <a href="#">UPLOAD</a>
FULL NAME*	<input type="text"/>	
PLACE OF BIRTH*	[ Select ] <input type="button" value="v"/>	
DATE OF BIRTH*	0000-00-00 <input type="text"/>	
DESIGNATION*	<input type="text"/>	 <a href="#">UPLOAD</a>
CORRESPONDENCE ADDRESS*	<input type="text"/> <input type="text"/> <input type="text"/>	
POSTCODE*	<input type="text"/>	
STATE*	[ Select ] <input type="button" value="v"/>	
TELEPHONE*	<input type="text"/>	
FAX*	<input type="text"/>	
EMAIL*	<input type="text"/>	

## Tool-tips for Establishment Licence Online Application

CONTACT PERSON DETAILS		SUPPORTING DOCUMENTS
Nationality	Please tick one box only.	
NRIC/ Working Permit	As appeared in the card/passport/permit.	<ul style="list-style-type: none"> <li>• Copy of NRIC/ Passport/ Work Permit</li> </ul>
Full Name	Name of the person that could be contacted	
Place of Birth	Name of the province, territory or country.	
Date of Birth	Year-Month-Date	
Designation	Nomination or appointment in the establishment.	<ul style="list-style-type: none"> <li>• Letter of Authorisation to authorise the Contact Person from Person Responsible</li> </ul>
Correspondence Address	Address for communication by the exchange of letters for contact person.	
Postcode	Example: 62300	
State	Please select the state.	
Telephone	Example: 603xxxxxxx	
Fax	Example: 603xxxxxxx	
Email	Email address of the contact person (Not establishment email)	

# APPLICATION FORM


## Section: QMS


QUALITY MANAGEMENT SYSTEM	SUPPORTING DOCUMENTS
Have you established your Quality Management System? <input checked="" type="radio"/> YES <input type="radio"/> NO	
Please indicate your establishment quality management system by clicking the appropriate box.	
<input checked="" type="checkbox"/> ISO 13485:2003	 <a href="#">UPLOAD</a>  <a href="#">Medical De...pdf</a>  <a href="#">Medical De...pdf</a>
<input checked="" type="checkbox"/> GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMD)	 <a href="#">UPLOAD</a>
Please provide Summary Report of certification audit prepared by Conformity Assessment Body (CAB) Name of C.A.B. <input type="text"/> C.A.B. Reg. No. <input type="text"/>	

QUALITY MANAGEMENT SYSTEM (IF YES)		SUPPORTING DOCUMENTS
ISO 13485	Please tick the relevant QMS.	<ul style="list-style-type: none"> <li>• Certificate of ISO: 13485</li> </ul>
GDPMD		<ul style="list-style-type: none"> <li>• Certificate of Good Distribution Practice For Medical Devices (GDPMD)</li> </ul>
Name of CAB	Registered with Authority (MDA)	<ul style="list-style-type: none"> <li>• Report of GDPMD/ISO 13485 audit prepared by Conformity Assessment Body (CAB)</li> </ul>
CAB Reg. No	As appeared in the certificate issued by MDA.	

# APPLICATION FORM

## Section: Medical Device Details, Attestation, Submission

MEDICAL DEVICE DETAILS		SUPPORTING DOCUMENTS
NAME OF MEDICAL DEVICE*	<input type="text"/>	
NAME OF MANUFACTURER*	<input type="text"/>	
NAME OF AUTHORISED REPRESENTATIVE (if applicable)	<input type="text"/>	
For multiple devices, please upload as Excel spread sheet. Template can be downloaded <a href="#">[here]</a> .		 <a href="#">UPLOAD</a>

ATTESTATION FOR ESTABLISHMENT LICENSING APPLICATION	SUPPORTING DOCUMENTS
Step 1: Click the 'Download' button to download the 	
Attestation for Establishment Licensing form	
Step 2: Fill in, stamp and sign the form	
Step 3: Upload the completed form	 <a href="#">UPLOAD</a>

APPLICATION SUBMISSION
<a href="#">PREVIEW APPLICATION FORM</a>
<a href="#">SUBMIT FORM</a>

## Tool-tips for Establishment Licence Online Application

### MEDICAL DEVICE DETAILS

Name of Medical Device	Name of product	• Provide only one medical device
Name of Manufacturer	An establishment who has full responsible to the product as mentioned above	
Name of Authorised Representative (if applicable)	Appointed by a manufacturer having a principal place of business outside Malaysia.	

### ATTESTATION FOR ESTABLISHMENT LICENSING APPLICATION

Please complete the Attestation Form with an official stamp and signature, and then upload as the supporting document here.	• Attestation for Establishment Licensing Form
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### APPLICATION SUBMISSION

Preview Application	An advance showing before submit the application	• PREVIEW APPLICATION FORM
Submit Form	Application will send to the MDA. No changes can be made once the application form is submitted	

# TEMPLATE FOR ATTESTATION BY APPLICANT FOR ESTABLISHMENT LICENSING

## ATTESTATION BY APPLICANT FOR ESTABLISHMENT LICENSING

[To be printed on Company Letterhead of Applicant]

Medical Device Authority

Date:

Dear Sir,

### Attestation for Establishment Licensing

I , identity card / passport number hereby attest that the information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.

I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Yours Sincerely,

Signature : \_\_\_\_\_

Name : \_\_\_\_\_

Official Stamp : \_\_\_\_\_

Date : \_\_\_\_\_

# Preview Application (Example)

## APPLICATION SUBMISSION PREVIEW (FORM ID: E406-20130715-899)

### **ESTABLISHMENT DETAILS**

ESTABLISHMENT	AUTHORISED REPRESENTATIVE
BUSINESS REG. NO	01234-X
ESTABLISHMENT NAME	MEDCAST TRAINING SDN BHD
ADDRESS	ARAS 5, MENARA PRISMA 62675 PUTRAJAYA
TELEPHONE	03-88922400
FAX	03-88922500
COMPANY WEBSITE	www.mdb.gov.my

### **PERSON RESPONSIBLE FOR ESTABLISHMENT**

NATIONALITY	MALAYSIA
NRIC	580703-10-5751
FULL NAME	ZAMANE BIN ABDUL RAHMAN
PLACE OF BIRTH	MALAYSIA
DATE OF BIRTH	1958-07-03
DESIGNATION	CHIEF EXECUTIFE
CORRESPONDENCE ADDRESS	ARAS 5, MENARA PRISMA 62675 PUTRAJAYA
TELEPHONE	03-8892 2551
FAX	03-8892 2500
EMAIL	zamane@mdb.gov.my

### **CONTACT PERSON DETAILS**

NATIONALITY	MALAYSIA
NRIC	841105-08-6768
FULL NAME	NUR SYAFURA BT ARIFFIN
PLACE OF BIRTH	MALAYSIA
DATE OF BIRTH	1984-11-05
DESIGNATION	ASSISTANT DIRECTOR
CORRESPONDENCE ADDRESS	ARAS 5, MENARA PRISMA 62675 PUTRAJAYA
TELEPHONE	03-8892 2400
FAX	03-8892 2500
EMAIL	syura@mdb.gov.my

### **QUALITY MANAGEMENT SYSTEM**

Do you have established you Quality Management System? YES	
Quality Management System	ISO 13485:2003
Name of C.A.B.	TUV SUD
C.A.B. Reg. No.	321903

Any enquiries regarding the establishment licensing and updating information of application please contact the following address:-

Establishment Unit  
Medical Device Authority  
Ministry of Health Malaysia  
Level 5, Menara Prisma  
Persiaran Perdana, Precinct 3  
62590 Putrajaya, Malaysia  
Telephone : 03 – 8892 2400  
Fax no. : 03 – 8892 2500

Information is also available from the website at <http://www.mdb.gov.my>

Thank you!

The image features the words "Thank you!" rendered in a vibrant, hand-drawn style. The letters are thick and rounded, with various colors and patterns. The word "Thank" is on the top line, and "you!" is on the bottom line. The letters are decorated with patterns like zig-zags, stripes, and dashed lines. There are several decorative flowers scattered around the text: a large pink flower with a yellow center and white dashed lines, a blue flower with a purple center, and another blue flower with a purple center. The background is a light blue gradient.