MDA/GL/004
October 2016

How to Apply for Renewal of Establishment Licence under Medical Device Act 2012 (Act 737)

Medical Device Authority

GUIDELINE FOR RENEWAL OF ESTABLISHMENT LICENCE

1. Introduction

The requirement for renewal of establishment licence is mentioned under the Section 24 of the Medical Device Act 2012 (Act 737). A licensee may apply for renewal of its establishment licence to the Authority not later than one year before the expiry date of the establishment licence.

2. Purpose

This guideline is prepared to provide guidance for renewal of establishment licence for establishments dealing with medical devices in Malaysia, in complying with the Medical Device Act and regulation.

3. Scope

This guideline applies to establishments as defined under Section 2 of the Medical Device Act 2012 (Act 737). This guideline covers renewal process and renewal fee.

4. Renewal Process

The process of renewal of establishment licence is described in Table 1.

4.1 Figure 1 shows the steps to be taken by an applicant when submitting renewal of establishment licence.

Figure 1: Steps to be taken when submitting renewal of establishment form

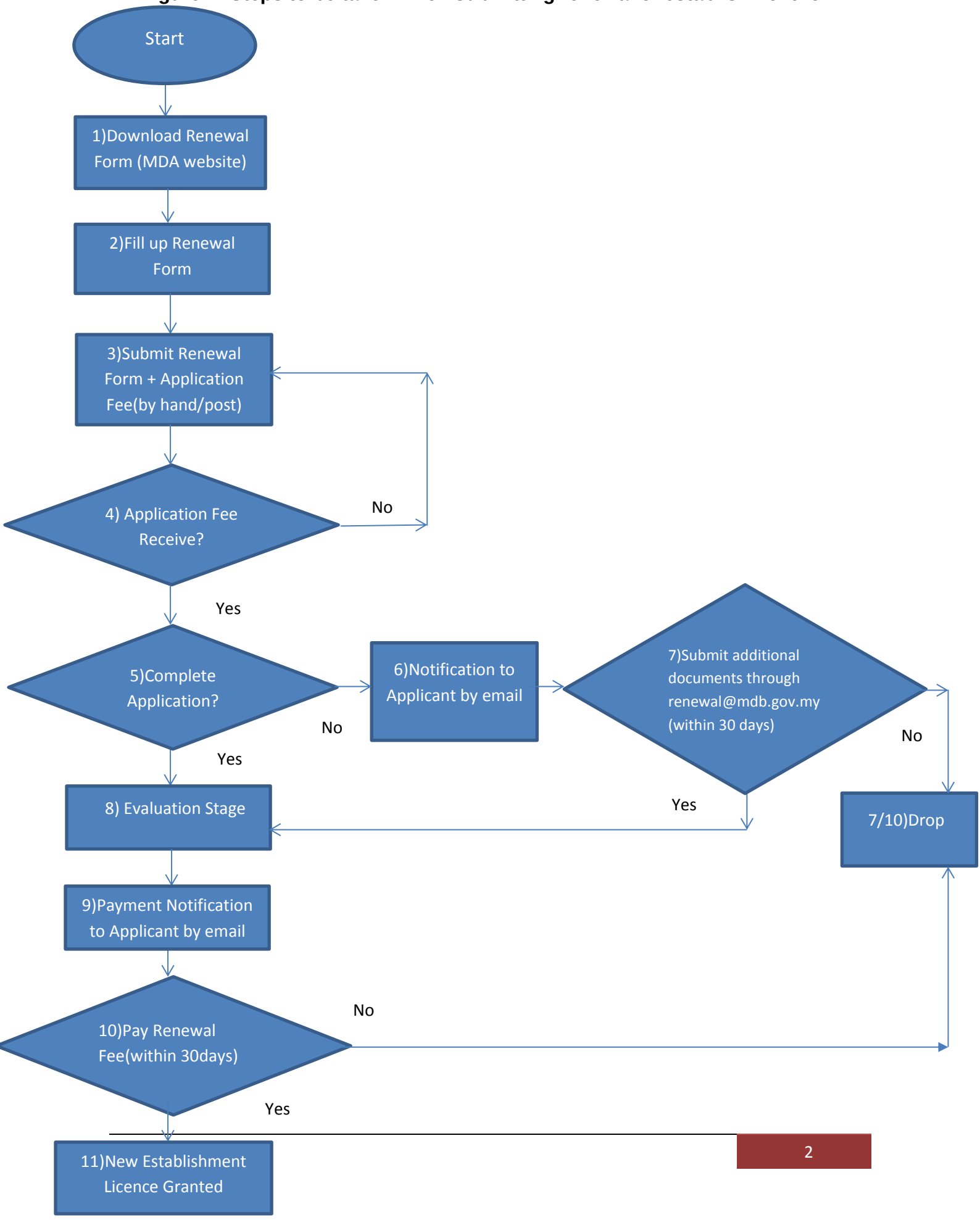

Table 1: Process of renewal of establishment licence

No	Processes	Descriptions
1.	Download Renewal Form (MDA website)	Please download the renewal form through www.mdb.gov.my
2.	Fill up Renewal Form	Please fill up the renewal form and attach the supporting documents as described in Table 2.
3.	Submit Renewal Form + Application Fee (by hand/post)	Please submit renewal form together with application fee by hand or post delivery. The application fee shall be paid through bank draft.
4.	Application Fee Receive	MDA will review the renewal application after application fee has been paid.
5.	Complete Application	Only complete application will be reviewed.
6.	Notification to Applicant	Please check your email as MDA will notify the applicant due to incomplete application.
7.	i)Submit additional documents through renewal@mdb.gov.my (within 30 days) ii) Drop	Please submit additional documents through renewal@mdb.gov.my within 30 days from. The renewal application will be dropped if additional documents are not received within 30 days
8.	Evaluation Stage	MDA will review the renewal application after receiving complete application.
9.	Payment Notification to Applicant by email	Please check your email as MDA will send the payment notification (payment advice).
10.	i)Pay Renewal Fee (within 30 days)	Please make a payment of renewal fee within 30 days from date of payment notification. The licence fee shall be paid through bank draft.

	ii) Drop	The renewal application will be dropped if renewal fee is not received within 30 days.
11.	New Establishment Licence Granted	New establishment licence will be granted upon renewal fee has been paid.

4.2 Filling in the renewal of establishment licence form

4.2.1 After downloading the renewal form through www.mdb.gov.my, establishment shall fill in the renewal application of establishment licence.

4.2.2 The following information and documents shall be furnished by the establishment in its application:

a) establishment details;

b) person responsible for establishment;

c) contact person;

d) quality management system (QMS); and

e) attestation for renewal of establishment

4.2.3 Applicant shall furnish all information and upload relevant supporting documents as required in the form.

4.2.4 The details on how to complete the Establishment Licence Application Form and information/documents to be furnished are explained in Table 2.

Table 2: How to complete Renewal Of Establishment Licence Form

(a)Establishment details	Descriptions	Documents to upload
(i) Type of establishment	Please indicate the type of your establishment: -Manufacturer/AR/Distributor/ Importer	Letter of Authorisation
(ii) Bumiputera Status	Please tick Yes or No column	Bumiputera Certifcate
(iii) Business registration number	Please provide business registration number of your company as issued by the	Form 9 /Form 13 /Borang D /Borang B /Borang 1

	Registrar of Company (ROC), Lesen perniagaan (Sabah) or Sijil Pendaftaran Ordinan Nama-nama Perniagaan (CAP64) (Sarawak)	
(iv) Establishment name	Please provide particulars and contact information of your establishment as requiredin the appropriate field.	
(b) Person responsible		
Details of person responsible	Please provide the particulars of the person responsible as required in the appropriate fields.	Appropriate identification document Malaysian citizen: i. identity card; and ii. Form 49; or letter of appointment of the person responsible signed by head of the establishment; Non-Malaysian: i. passport; and ii. employment pass; and iii. Form 49; or letter of appointment of the person responsible signed by head of the establishment.
(c) Contact person		
Details of contact person	Please indicate whether contact person is the same person as the responsible person. If the contact person is not the same person as person responsible, please provide the particulars of the contact person as required in the appropriate fields.	Letter of authorisation of the contact person signed by the person responsible. *[If contact person is not the same person as the person responsible]*

(d) Quality management system (QMS)		
Details on QMS	If your QMS have been certified by registered CAB, please indicate the QMS that you have established in the appropriate box, i.e. MS ISO/ ISO 13485 for manufacturer or GDPMD for other establishment types, and provide the name and registration number of the CAB.	i. Audit report; and ii.Certificate of conformity issued by the CAB.
(e) Attestation for establishment licensing application		
Submission of attestation	Fill in, stamp and sign the form by person responsible and print on company letterhead;	Completed attestation form

5. Renewal of establishment licence

Licensee(s) may apply for renewal of establishment licence not later than one year before the expiry date of the establishment licence. However, Licensee(s) are required to perform re-certification audit as GDPMD certificate must be **valid** on the expiry date of current licence.

5.1 Renewal fee

i) application renewal fee: RM 200.00.

ii) licensing renewal fee:Table 3 shows the fees for different type of licence renewal.

Table 3: Fees for renewal of licence

Type of licence	Renewal Fee (MYR)
Manufacturer	2,000.00
Authorised Representative (AR)	2,000.00
Importer	1,000.00
Distributor	1,000.00

iii) Table 4 shows the fees for renewal of multiple licences

Table 4: Fees for renewal of multiple licences

Type of licence	Renewal Fee (MYR)
Manufacturer + distributor	2,000.00
Manufacturer + AR	4,000.00
AR + Distributor + Importer	2,000.00
Importer + Distributor	1,000.00

5.2 Payment

i) All fees shall be paid through bank draft. Cash will not be accepted. We will not be responsible for the cash sent or brought to MDA.

ii) The bank draft must be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and send to MDA office.

iii) Payment must be made within 14 days after date of payment advice issued from MDA.

ANNEX A

Template for Letter of Authorization

A.1 Authorised Representative

The template for Letter of Authorisation for Authorised Representative as presented below shall be used.

[To be printed on Company Letterhead of the Manufacturer]

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 Regulations 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 condition imposed by the Authority.

We undertake to provide all the necessary support and assistance to the distributor/importer 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 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,

[Signature]

[Full Name]

[Designation of Senior Company Official]

[Company stamp]

A.2 Distributor

The template for Letter of Authorisation for Distributor as presented below shall be used.

[To be printed on Company Letterhead of the AR/Manufacturer]

Medical Device Authority

Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [name of **Distributor]**

We, [name of the AR/Manufacturer*], as the Authorised Representative/Manufacturer* of the medical device listed in Attachment 1, hereby authorise [Company name (Registration Number) or Person name (IC Number) and address], as the distributor to distribute the listed medical devices on our behalf.

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 condition imposed by the Authority.

We undertake to provide all the necessary support and assistance to the distributor/importer 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 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,

[Signature]

[Full Name]

[Designation of Senior Company Official]

[Company stamp]

* Choose one

A.3 **Importer**

The template for Letter of Authorisation for Importer as presented below shall be used.

[To be printed on Company Letterhead of the AR]

Medical Device Authority

Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [name of Distributor]

We, [name of the AR], as the Authorised Representative of the medical device listed in Attachment 1, hereby authorise [Company name (Registration Number) or Person name (IC Number) and address], as the importer to import the listed medical devices on our behalf.

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 condition imposed by the Authority.

We undertake to provide all the necessary support and assistance to the distributor/importer 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 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,

[Signature]

[Full Name]

[Designation of Senior Company Official]

[Company stamp]

Template For Attestation Form

A4. Attestation By Person Responsible 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, 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 : _____

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 5, Menara Prisma
No. 26, Jalan Persiaran Perdana
Precint 3, 62675 Putrajaya
MALAYSIA
T: (03) 8892 2400
F: (03) 8892 2500
Website: www.mdb.gov.my