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MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES FOR THE PURPOSE OF DEMONSTRATION FOR MARKETING OR EDUCATION

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following- a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
Fax: (03) 8230 0200
Email: mdb@mda.gov.my
Website: https://portal.mda.gov.my/

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES FOR THE PURPOSE OF DEMONSTRATION FOR MARKETING OR EDUCATION

1. Introduction

According to Section 5 and 15 of Medical Device Act 2012 (Act 737), the importation, exportation, or placement of a medical device in the Malaysia market requires the medical device to be registered and establishments which include manufacturers, authorised representatives, distributors, or importers to be licensed.

However, the Medical Device (Exemption) Order 2016 which has been gazetted on 18 April 2016 has provided for an exemption of both medical devices registration and establishment license if the medical device is for the purpose of demonstration for marketing or for the purpose of education.

Prior to supplying a device eligible for exemption, the manufacturer or importer of the device shall submit a notification to Medical Device Authority for an exemption. An acknowledgement on the notification issued by the Authority then permits the device to be supplied or imported lawfully for the specific defined use.

This guidance document explains the process of notification, including the requirements for obtaining the permission from the Authority to import and/or supply these medical devices. It also specifies the responsibilities and obligations of the importer/manufacturer when dealing with this category of medical device.

2. Scope and application

This guidance document specifies requirement on notification for importation and/or supply of medical devices intended solely for the purpose of demonstration for marketing or for the purpose of education. It applies to all applicants who wish to import and/or supply these medical devices, of any risk classification into Malaysia.

3. Terms and definitions

For the purposes of this document, the terms and definitions in ACT 737, the regulations under it and the following terms and definitions apply.

3.1 applicant

Applicant can be either any person/company/organization who wish to import and/or supply medical device for the purpose of demonstration for marketing or for the purpose of education.

3.2 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.3 date of importation

Date on which the medical device arrives within the limits of the port in Malaysia with intent then and there to unlade such merchandise.

3.4 export

Means to bring or cause to be brought out of Malaysia.

3.5 import

means to bring or cause to be brought a medical device manufactured in another country or jurisdiction, into Malaysia by land, sea or air

3.6 incident

means any malfunction or deterioration in the characteristics or, performance of medical device or inadequacy in its labelling, which either has caused or could have caused or contributed to death or a serious deterioration in health of the patient, user or third party

3.7 medical device

a) Any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of:

(i) diagnosis, prevention , monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;

(iv) support or sustaining life

(v) disinfection of medical device; or

(vi) providing information for medical or diagnostic purpose by means of *in-vitro* examination of specimens derived from the human body which does not achive its primary intended action in or on the human bosy by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, publis health or public risk, declare to be a medical device by order published in the *Gazette.*

3.8 place in the market

Means to make available a medical device in return for payment or free of charge with a view to distribution, using, supplying or putting in into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device.

4. Eligibility for notification of exemption

The medical device as described in Table 1 are eligible for notification of exemption.

Table 1. Description of medical devices for demonstration and/or education purposes.

No.	Category of exemption	Description
1.	Medical device for the purpose of demonstration for marketing.	a. an activity to introduce a medical device to the vast market e.g. in trade fairs or exhibition or scientific or technical gatherings which is not to be used on human for a purpose to gather marketing information in a specific period of time before the device being registered. In the period of marketing demonstration, all marketing activities such as promoting and information distribution such as posters, notices, brochures, pamphlets, banners, buntings, photographs, video clips with limited information specifically on device's specification and features are allowed. b. For IVD device, it also includes reliability or quality testing activity(ies), where the result obtained are solely used for the purpose of enhancing trust and confidence towards the device(s). In this instance, the result cannot be used to support or reject patient's diagnosis / treatment.
2.	Medical device for the purpose of education.	An activity that is purely for teaching, training or educating people without having any kind of intention related to promoting or marketing and not to be used on human or for the purpose of diagnosis/treatment.

5. Notification process

An applicant who wishes to import and/or supply of a medical device for the purpose of demonstration for marketing or education shall notify the Authority by following the steps as summarized in **Annex A**.

Notes:

1. The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not eligible for this medical device notification.

2. The applicants who require confirmation if their product is a medical device may refer to guidance document MDA/GD/0006 Definition of Medical Device or submit the 'Product Classification application form' to classification@mda.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website https://portal.mda.gov.my/industry/product-classification.html.

5.1 Verification with other controlling agencies.

The notification to the Authority does not exempt the applicant from abiding to any other law or regulations in Malaysia.

For example:

a) Refer to the Royal Malaysian Customs department for more information about the importation and declaration procedures; and

b) Refer to Atomic Energy Licensing Board (AELB) for more information about application for irradiating apparatus demonstration/exhibition procedure.

5.2 Submission of notification

5.2.1 New notification

a) Notification shall be submitted to the Authority at least **14 working days** prior to importation or supplying the medical device;

b) Application for 'Notification of Medical Device for the purpose of Demonstration for Marketing or for Education Purpose' shall be made online through the MeDC@St system. Supporting documents shall be submitted with this notification;

c) To make a notification, an applicant shall create a MeDC@St account (refer **Annex B** or https://portal.mda.gov.my/documents/image/1094-flowchart-notificationakaun/file.html). After the account is created, applicant can log in to the system and complete the notification;

   (i) The details on how to complete the notification of medical device for demonstration are explained in **Table 2**.

   (ii) The details on how to complete the notification of medical device for the purpose of education are explained in **Table 3**.

Note: Please complete all information requested on this notification (All fields are mandatory unless stated otherwise).

d) For medical device for the purpose of demonstration, each notification submitted can be for more than one medical devices and locations, however this permission is valid only for a maximum of 90 days from the date of importation;

e) For medical device for the purpose of education, multiple shipments are allowed for the approved quantity of medical device in the notification and within the permissible period of importation; and

f) Quantity of medical device to be imported shall be appropriate to the declared purpose and the applicant shall provide justification or description on this requirement.

Note: All periods are in calendar days unless specified as working days

5.2.2 Request for extention period of Medical Device for Demonstration/marketing.

a) A subsequent notification may be made of any applicant who wish to request for extension of demonstration period after the expiry of the first notification. This process follows the same procedure as described in new notification except that certain information e.g. supporting document for medical device may not be required.

b) Any subsequent notification shall be submitted at least **14 working days** before the expiry date of the first notification. Permission for subsequent notification is granted only to a maximum of 90 days and demonstration location shall be different from the first notification.

5.2.3 Post handling of medical devices for the purpose of demonstration.

After the demonstration period has expired, the applicant shall:

a) ensure that these medical devices are properly disposed of or exported out of Malaysia.

b) submit ‘Post handling’ Notice via MeDC@St system no later than 30 days from end of the demonstration period. Applicant will receive an acknowledgement email from the system after submission of the post handling notice.

c) keep relevant record as a proof for the disposal or exportation of those medical device.

Table 2 : Explanation on the information/particulars required in the Notification of Medical Device for Demonstration Form

Information/ Particulars	Explanation and Documents to be Submitted

I. New notification	First or fresh notification.
II. Extension	Application made for extension of demonstration period.
III. Post handling	Applicant shall submit the post handling notice within 30 days after the demonstration period permitted by Authority has expired.

I. NEW NOTIFICATION	
Section A	**General Information**
1. Period of demonstration Period of medical device to be used for demonstration.	
1a. Start date	Period of medical device to be used for demonstration. Maximum period is 90 days from the date of importation.
1b. End date	
1c. Event Details (repeat as needed)	
i. Type of event	Please state type of event for the purpose of the demonstration, e.g. trade fairs or exhibition or scientific or technical gatherings.
ii. Demonstration Location	Please state the name and address of the demonstration location. (Specific location of the event).
iii. Demonstration Date	Please state the date of the event to be held.
iv. Please provide supporting document	Please provide event details, e.g. brochures, official website, or letter. Supporting document shall be in pdf format.
2. Details of Applicant	
a) Name of person responsible **b) NRIC/ Passport no.** **c) Designation**	Please state the name and details person responsible in the organisation. Criteria for person responsible: a) Shall be from top management; i) Person responsible shall have the overall control and have the authority to make decision; ii) Depending on the organisational structure of the establishment, person responsible may include

Information/ Particulars	Explanation and Documents to be Submitted
	Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.
d) Name of contact person	• Name and details of person in charge of making the notification. • Contact person is the person appointed/authorised by the organisation by the person responsible, and acts as a liaison between the Authority and the organisation in relating to this notification. • Person responsible may also be contact person.
e) Telephone no.	Please state the telephone number of contact person.
f) Email address	Please state the email address of contact person.
g) Organisation Information	
i) Organisation /company name	Please state the name of your organization/company.
ii) Organisation /company address	Please state the address of your organization/company.

iii) State	Please choose the state of where your organization/company is.
iv) City	Please choose the city of where your organization/company is.
3. Role of Establishment (if applicable)	
i) The type of your 'Establishment'	If your company hold an 'Establishment License' under the Authority, please tick the appropriate box.
ii) Status of your establishment	Please tick the appropriate box and state accordingly either license application ID or Establishment license certificate number.
Section B	**Medical Device Information**
1. Please provide details of the medical device(s) (Repeat as needed)	
a) Medical Device Name	Name given to the medical device(s) as per label.
b) Brand/ Model	Name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers.
c) Manufacturer's Name	Name of manufacturer. Note: Manufacturer according to manufacturer term as specified in Section 2, Act 737 and it appears on the device label.
d) Description of Medical Device	A thorough explanation on how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation.
e) Intended use of Medical Device	Use of the medical device for which it is intended by the manufacturer, according to the data supplied by the manufacturer in the instructions for use as well as the functional capability of the device.

Information/ Particulars	**Explanation and Documents to be Submitted**
f) Class and Classification rule	The risk associated with medical device according to the Classification Rules in First Schedule of MDR2012. Note: The applicant who require further guidance on the classification may refer to the following documents - a) MDA/GD/0009: Guidance on The Rules of Classification for General Medical Devices; b) MDA/GD/0001: In-Vitro Diagnostic (IVD) Medical Device Classification System. The guidance documents are available at MDA website https://portal.mda.gov.my/doc-list/guidance-document.html.
g) Total Quantity to be Imported	Please state total quantity to be imported.
h) Marketing Approval Status	Please select the status of pre-market clearance/approval from foreign countries.

Click save button to save the medical device details.

To update site details per each medical device, click the 'update site details'.

i) Update site details (Add more sites as needed)	
i1. Site Name	Please state the specific location name for the event.
i2. Site Address	Please state the specific full address for the event.
i3. Quantity Supplied	Please state total quantity of device per location.
2. Supporting Documents	Please upload supporting document for medical device: - sample of the medical device packaging label/promotional material (such as brochure, pamphlet or catalogue) that contain information about the intended use/general description/mode of action of the medical device.
Section C	**Attestations and Declaration**
Attestations and Declaration	(A declaration which recites duties, responsibilities and obligations of applicant and shall be made by person responsible.) Please read and understand all the declaration and tick all the boxes.
II. EXTENSION	
1. Period of Demonstration	• Please select the start date and the end date for demonstration. • Maximum period for extension is 90 days.
2. Add event details	Applicant may add new event and location.
2a. Type of event	Activity purely intend for demonstration/presentation or exhibits in trade shows, fairs, and exhibitions.
2b. demonstration location	Please state the name and address of the demonstration location. (Specific location of the event).
2c. Demonstration date	Please state the date of the event to be held.
3. Update event details	Please update the date of demonstration for previous notification with no change of event and location. (if applicable)
Information/ Particulars	**Explanation and Documents to be Submitted**
4. Event details	Please upload event details, e.g. brochures, official website, or letter.
III. POST HANDLING	
1. Add post method	Please specify the method use for post handling of the unregistered medical device.
2. Supporting document	Please provide supporting document related to the post handling process used.

No	**Particulars**	**Explanation and Documents to be Submitted**
a)	Dispose of	Document of disposal.
b)	Import out	Export out declaration to custom.
c)	Registration	Medical device registration certificate.
d)	New notification	Acknowledgement on Notification letter

3. Declaration	Please tick all boxes to made declaration on the information provided.

Table 3 : Explanation on the information/particulars required in the Notification of Medical Device for the purpose of Education

Information/ Particulars	Explanation and Documents to be Submitted
New notification	First or fresh notification.
Section A	**Education / training centre details**
1. Course Name / Training Programme	Please state the title of course /training programme.
2. Centre Name	Please state the learning centre name.
3. Location Address	a. Please write full address of the location. b. Please select the appropriate state and city. c. Please write the postcode of the location.
4. Department	Please state the specific name of department, faculty, and school where the medical device will be placed. (state N/A if not applicable)
5. Faculty	
6. School	
7. Person in-charge Name	Please state the name of the person in-charge of the programme.

Information/ Particulars	Explanation and Documents to be Submitted
8. Contact No	Please write contact number of the person in-charge of the programme.

9. Justification	Please provide explanation why the training is required and state reason why it has to be specific medical device which are not available in Malaysian market. Note: There shall be no similar medical device available in Malaysia market. The applicant shall state reason on why it has to be the specific medical device.
10. Supporting Documents	Please upload supporting document, i.e. programme brochure/course.
11. Details of applicant	
a) Name of Person Responsible	Please state the name, Identification number/ passport number and designation of top management of a company or the person having the overall control and have the authority to make decision.
b) NRIC/Passport No	
c) Designation	
d) Name of contact person	Name and details of person in charge of making the notification.
e) Telephone no.	Please state the telephone number of contact person.
f) Email address	Please state the email address of contact person.
g) Organisation Information	
v) Organization /company name	Please state the name of your organization/company.
vi) Organization /company address	Please state the address of your organization/company.
vii) State	Please select the state of where your organization/company is.
viii) City	Please select the city of where your organization/company is.
12. Role of Establishment (if applicable)	
iii) The type of your 'Establishment'	If your company hold an 'Establishment License' under the Authority, please tick the appropriate box.
iv) Status of your establishment	Please tick the appropriate box and state accordingly either license application ID or Establishment license certificate number.
Section B	**Medical Device Information**
1. Please provide details of the medical device(s)	

Information/ Particulars	**Explanation and Documents to be Submitted**
a) Medical Device Name	Name given to the medical device(s) as per label.

b) Brand/ Model	Name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer‘s medical device distinct from those of other manufacturers.
c) Manufacturer's Name	Name of manufacturer. Note: Manufacturer according to manufacturer term as specified in Section 2, Act 737 and it appears on the device label.
d) Description of Medical Device	General description of the device which explain how the device function, the basic scientific concept that form the fundamentals for the devices, the component materials and accessories used in its principle of operation.
e) Intended use of Medical Device	Use of the medical device for which it is intended by the manufacturer, according to the data supplied by the manufacturer in the instructions for use as well as the functional capability of the device.
f) Class and Classification rule	The risk associated with medical device according to the Classification Rules in First Schedule of MDR2012. Note: The applicant who require further guidance on the classification may refer to the following documents - a) MDA/GD/0009: Guidance on The Rules of Classification for General Medical Devices; b) MDA/GD/0001: In-Vitro Diagnostic (IVD) Medical Device Classification System. The guidance documents are available at MDA website https://portal.mda.gov.my/doc-list/guidance-document.html.
g) Total Quantity to be Imported	Please state the total quantity for import.
h) Period of importation	For multiple importation, the subsequent importation shall be within 180 days from the date of the acknowledgement on notification letter.
i) Marketing Approval Status	Please select the status of pre-market clearance/approval from foreign countries.
2. Supporting Documents	Please upload supporting document for medical device: - sample of the medical device packaging label/promotional material (such as brochure, pamphlet or catalogue) that contain information about the intended use/general description/mode of action of the medical device.
Information/ Particulars	**Explanation and Documents to be Submitted**
Section C	**Attestations & Declaration**
Attestations and Declaration	(A declaration which recites duties, responsibilities and obligations of applicant and shall be made by person responsible.) Please read and understand all the declaration and tick all the boxes.

6. Administrative charge and Reviewing Process

6.1 Each notification shall be subject to an administrative charge of RM 300.

6.2 If, after consideration of all the information provided, the Authority considers that the information provided is incomplete, the Authority may request the missing/incomplete information from the applicant. Any additional information, particulars or documents required by the Authority shall be provided by the applicant within **14 working days** from the date of request by the Authority.

6.3 Failure to meet any of the criteria and/or to reply within the specified timeframe may result in rejection of the notification. The fee for the notification is non refundable. However it would not affect the right of the applicant to make a fresh notification.

6.4 The Authority has the right to withdraw a written Acknowledgement on Notification if in its opinion, there has been a breach or non-compliance with the specified terms and conditions and/or duties and responsibilities of the applicant.

7. Duties and responsibilities of applicant

The applicant shall be fully responsible for handling the unregistered medical device during the period of the demonstration for marketing or for the purpose of education, including:

a) used only in accordance with the purpose as declared in the Notification submission;

b) medical devices shall be prominently indicated with labels or signage **"For Demonstration or Education Purpose Only. Not For Use On Human"**.

c) ensuring that the medical devices are not used on human or used to provide result or information to support or reject any patient's diagnosis/treatment;

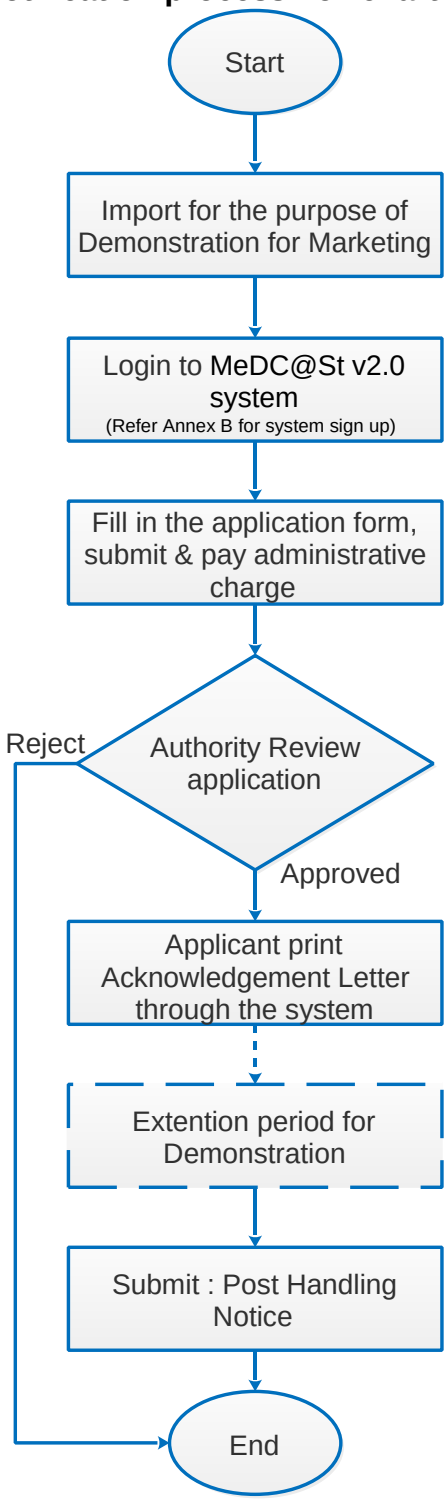
d) comply with any directions issued by the Authority from time to time and allow for inspection from Authority at any time without prior notice;

e) keep all information pertaining to this unregistered medical device at the premises and shall be made available upon request by the Authority at any time; and

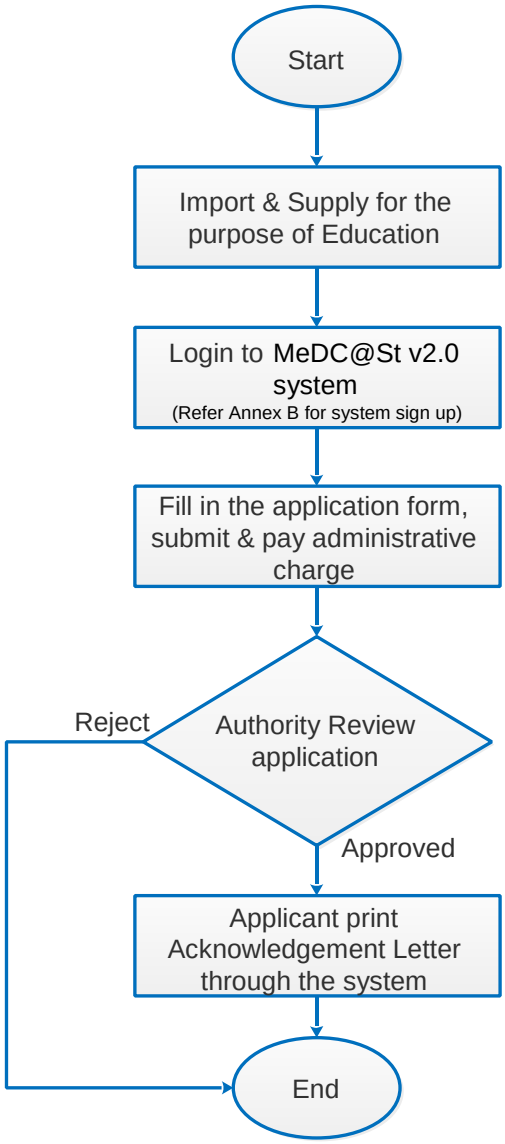
f) distribution of free samples is prohibited.

ANNEX A (informative)

Demonstration for marketing notification process flowchart

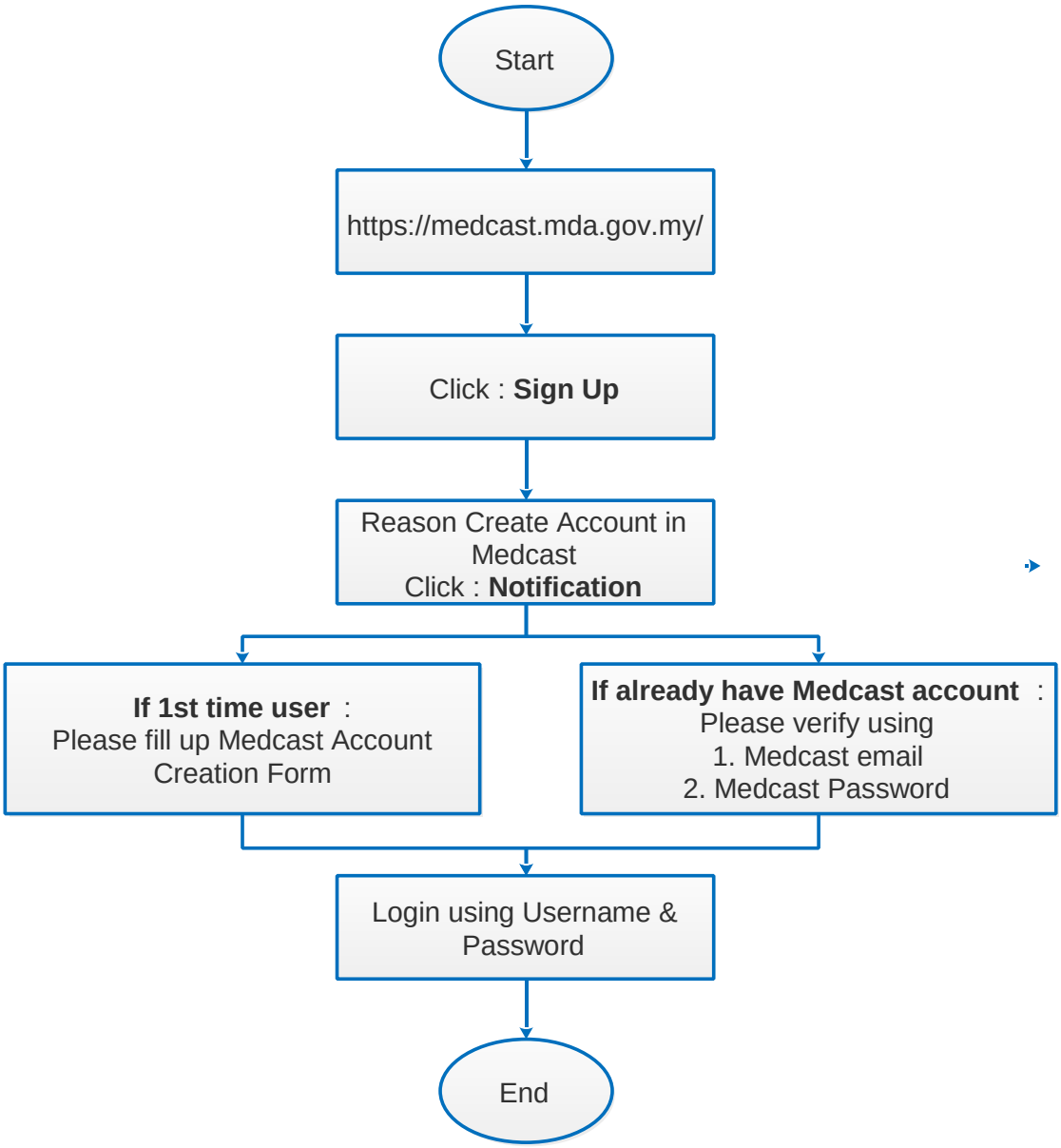


Education notification process flowchart



ANNEX B (informative)

MeDC@St account creation process flowchart


Start
https://medcast.mda.gov.my/
Click : **Sign Up**
Reason Create Account in Medcast
Click : **Notification**
If 1st time user :
Please fill up Medcast Account Creation Form
If already have Medcast account :
Please verify using
1. Medcast email
2. Medcast Password
Login using Username & Password
End

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: https://portal.mda.gov.my/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