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MEDICAL DEVICE GUIDANCE DOCUMENT

COVID-19 RTK (SELF-TEST) - REQUIREMENTS

In lieu of the rise of the emergency situation where the Covid-19 pandemic has occurred, the Medical Device Authority (MDA) has published this guidance document without seeking public comment as per the usual practice. This is to enable the guidance document to be published in the shortest possible period. MDA will not seek public comment prior to implementing a guidance document if the Authority determines that prior public participation is not feasible or appropriate.

MDA/GD/00xx

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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);

b) Medical Device Regulations 2012;

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and

d) Medical Device (Advertising) Regulations 2019.

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 event 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.

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COVID-19 RTK (SELF-TEST)- REQUIREMENTS

1. Introduction

Section 5 (1) of the Medical Devices Act 2012 (Act 737) requires all medical devices to be registered before it can be imported, exported or placed on the market. There are many types of test kits available in the Malaysian market that offer a range of screening tests. IVD test kits are regulated as medical devices, as defined in Section 2 of Act 737. It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

Since the outbreak of COVID-19 in Malaysia, MDA has taken the approach of granting conditional approval to establishments wishing to supply Covid-19 self-test kits in view if the pandemic situation.

This document is intended to provide guidance to establishments on the requirements for placement of Covid-19 RTK (self-test) in the market. It can also be a good reference for healthcare facilities and public dealing with Covid-19 RTK (self-test).

Conditional approval application procedure for Covid-19 RTK (self-test) is available at MDA Guideline Conditional Approval For COVID-19 Rapid Test Kit (Self-Test) (MDA/GL/05).

2. Scope and application

This guidance document specifies requirements for conditional approval of Covid-19 RTK (self-test) to be placed in the Malaysian market, based on Circular Letter No.1/2021.

This guidance document does not apply to Covid-19 test kits for Professional Use Only.

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 home use medical device

A home use medical device is a medical device labelled for use in any environment outside a professional healthcare facility and intended for use by healthcare

professionals and/or lay persons. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes.

Notes:

1. Lay person includes patient (care recipient), caregiver (includes non-healthcare professionals), or family member that directly uses the device or provides assistance in using the device.

2. A home use medical device requires adequate labelling for the user and may require training for the user by a healthcare professional in order to be used safely and effectively.

3.2 instructions for use (IFU)

Information provided by the manufacturer to inform the device user of the medical device proper use and of any precautions to be taken.

3.3 intended use/ purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.4 label

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

NOTE. The definition above refers to the human readable label.

3.5 labelling

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

NOTES:
1. Labelling can also be referred to as "information supplied by the manufacturer."
2. Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be accessed (such as through a website).

3.6 lay person

Individual that does not have formal training in a specific field or discipline. (Source: ISO 18113-1).

3.7 manufacturer

As defined in Section 2 of Act 737.

3.8 user

The person, either professional or lay, who uses a medical device.

4. Requirements

4.1 Requirements on establishment

4.1.1 Establishments shall:

a) have a valid MDA establishment license with in-vitro diagnostic (IVD) scope on the Good Distribution Practice of Medical Device (GDPMD) certification.

b) apply for conditional approval and place the self-test kits into the market upon receiving Conditional Approval Letter from the Authority. Refer MDA Guideline, MDA/GL/05, *Conditional Approval For COVID-19 Rapid Test Kit (Self-Test).*

c) comply with the labelling requirements as set out in the Sixth Schedule of the Medical Devices Regulations 2012.

d) also provide the labelling information as follows:

   i) methods of reporting (for the users) to medical practitioners/ relevant authority (if positive/ negative/ invalid); and

   ii) clear disposal methods.

e) collect data related to safety and performance of the medical device and shall submit the report to the Authority on a regular basis or when it is required by the Authority. The template of the data collection on safety and performance can be referred in Annex A.

f) establish adequate precautions and control to prevent deterioration or damage of the medical devices up until the point of use.

g) ensure the delivery of medical devices adhere to the conditions specified by the manufacturer.

h) keep track and document all medical devices supplied, recording details on:

i) purchaser information (name, and contact information);

   ii) batch or lot number and/or model and serial number; and

   iii) date of transactions and delivery.

j) provide QR code on COVID-19 RTK (self-test) label to redirect to instructions for use, disposal method and reporting mechanism together with medical device information such as name, brand, conditional approval letter reference number, batch /lot number /serial number. The QR code will also direct the purchaser to a form for capturing information on:

   i) purchaser information (name, and contact information);

ii) date and time of purchase; and

iii) the premise where the purchase is made.

k) keep all information pertaining to this medical device including documents such as invoices, delivery order (DO), and summary of distribution record at the premises and shall be made available upon request by the Authority.

4.1.2 Establishments should, as appropriate:

a) provide video tutorial as well as infographics to facilitate users understanding on safe use of self-test kit, disposal methods and actions to be taken if test results are positive/negative/invalid; and

b) provide the labelling in Bahasa Malaysia

4.2 Selling of Covid-19 RTK (self-test)

4.2.1 The Covid-19 RTK (self-test) can ONLY be sold by:

a) licensed pharmacies licensed with Pharmaceutical Services Division, MOH;

b) private healthcare institutions (clinic or hospital) licensed with Private Medical Practice Control Section, MOH (CKAPS);

c) other premises registered with KPDNHEP;

d) establishments to another licensed establishments (with IVD scope in GDPMD);

e) establishment to individual user; and

f) establishments to companies/ government or private organisations/ educational institutions for the purpose of supplying for use by workers, personnel, or students.

4.2.2 Selling of Covid-19 RTK (self-test) by individuals is strictly prohibited.

4.3 Online selling

Covid-19 RTK (self-test) can be sold via the online platform **by 4.2.1 a), b), d), e) and f).** However, deliveries shall be carried out by suitable logistic providers with assurance of safety and performance.

The responsible online platform owner should provide a mechanism to record distribution and sale information to the public to assist the MDA in collecting information on test results made by the public.

4.4 Storage and stock handling

The establishment shall ensure that proper trainings are provided and sellers of Covid19 RTK (self-test) comply with the requirements of storage and handling as follows:

a) stored and handled in accordance with the manufacturer's instructions to ensure integrity of Covid-19 RTK (self-test);

b) establish adequate precautions and control of the storage environment to prevent deterioration or damage of the test kits; and
c) broken or damaged medical device shall be identified and disposed off according to the manufacturer's requirements.

4.5 Disposal of test kits

The establishment shall ensure proper procedures are in place on the disposal method, as described in the contents of labelling.

It is encouraged that the disposal instructions are provided in the form of graphics or videos so that they can be more easily understood by consumers (general public).

4.6 Advertisement

According to Section 44 of Act 737, no person is allowed to advertise unregistered medical device, and as such Covid-19 RTK (self-test) are not allowed to be advertised. Logo of the Medical Device Authority (MDA) is prohibited to be placed on the device, its labelling or other materials associated with the sales of the device.

However, the following are allowed:

a) materials that only contain price, product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims or descriptions; and

b) materials which only contain exact replica of the packaging (not size but shape and content) as approved by the Authority during conditional approval.

4.7 Post market responsibility

4.7.1 Establishments are required to comply with post market obligations. The establishment shall establish and maintain a post-market surveillance system to monitor the traceability of the medical device throughout the supply chain.

4.7.2 The Chapter 3 of the Medical Devices Act 2012 (Act 737) and the Medical Devices (Duties and obligations of establishment) Regulations 2019 provided for requirements on post-market surveillance and vigilance. Establishments shall carry out their responsibilities to monitor and continuously ensure the safety and performance of their medical devices in the market.

4.7.3 Establishments may also refer to the following documents:

a) MDA /GD/0011, *Complaint Handling*;

b) MDA /GD/0012, *Distribution Record*;

c) MDA /GD/0013, *Field Corrective Action;*

d) MDA /GD/0014, *Mandatory Problem Reporting;* and

e) MDA /GD/0015, *Medical Device Recall.*

Annex A
(informative)

Monthly Reporting of Covid-19 Test Kit to Medical Device Authority

No.	Information needed	Method
Part I	**SURVEILLANCE REPORT**	
	Email address	e-form
	Establishment name:	e-form
	Establishment license number:	e-form
	Reporting month:	e-form
	Type of route / approval - note: if you obtained both type of approval, report separately for each type.	e-form
	Device name:	e-form
	MDA approval number:	e-form
	Batch / lot number:	e-form
	What is the most frequent complaint received for this device: (*the authority has set out to classify the main complaints into these 4 categories only). Please select not applicable if you received no complaint or complaint is not related to the	e-form
	categories. Number of complaint (based on most frequent complai nt mentioned in earlier question) for this month. *type n/a if not applicable	e-form
	Corrective action taken (*for the major complaint): please type n/a if not applicable	e-form
	Preventive action taken (*for the major complaint): please type n/a if not applicable	e-form
	Status of corrective and preventive action taken (*for the major complaint): Ongoing/Closed	e-form
	Surveillance report template:	*Upload document templates*
Part II	**PERFORMANCE REPORT**	
	Device name:	e-form
	MDA approval number:	e-form
	Batch / lot number:	e-form
	Performance validation test report	e-form
	Performance validation report template upload:	*Upload document*

Part III	**DISTRIBUTION RECORD**	*templates*
	Device name:	e-form
	MDA approval number:	e-form
	Batch/lot number:	e-form
	Importation date:	e-form
	Distribution date:	e-form
	Distribution location:	e-form
	Distribution quantity:	e-form
No.	**Information needed**	**Method**
Part III	**DISTRIBUTION RECORD**	
	DELIVERY ORDER RECORD: *You may upload your Delivery Order record here.	*Upload document templates*
	Distribution record involving multiple location and multiple device - template upload	*Upload document templates*
Attestation	I hereby attest that the information and attachment provided for this reporting is correct, complete and current to this date.	e-form
	I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.	e-form

MEDICAL DEVICE AUTHORITY

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