MDA/GL/05

July 2021

Second Edition

Guidelines for implementation of medical device regulatory system

CONDITIONAL APPROVAL FOR COVID-19 RAPID TEST KIT (SELF-TEST)

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

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

Preface

This Guideline 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 Guideline 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 Guideline 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.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guideline 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 guideline 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 guideline 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
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my

CONDITIONAL APPROVAL FOR COVID-19 RAPID TEST KIT (RTK) (SELF-TEST)

0 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.

Along with current technology, several types of Covid-19 test kits are produced with different features where detection can be done independently by following the instructions for use (IFU) set by the manufacturer.

Taking into account the importance of public health and safety, MDA needs to establish a temporary approval method for Covid-19 RTK (self-test) immediately so that these medical devices can be supplied and used to further facilitate the detection and control of Covid-19 infections in the country.

This Covid-19 RTK (self-test) can be obtained from pharmacy counters and can be used by the public according to the guidelines provided and can produce results quickly. This is seen to help individuals in obtaining certainty of the status of the infection before seeking advice from a medical practitioner for further action. This also helps reduce the burden of health workers.

The normal registration process is seen to take a long time, including the process of assessing compliance with technical documents as well as a complete clinical study conducted on a medical device. Furthermore, at present, there is no technical code to classify such medical devices for the purpose of conformity assessment by CABs and no registered CAB can conduct conformity assessment for Covid-19 test kits.

In reference countries, the Covid-19 RTK (self-test) products have been granted temporary or conditional approval through Emergency Use Authorization (EUA) in the United States and Provisional/Interim Authorization in the UK and Singapore.

1 Scope and application

This guideline provides clarification on Covid-19 self-test kit that are regulated under the Medical Device Act (Act 737). This document is applicable to establishments, healthcare facilities, and public dealing with Covid-19 self-test kits.

2 Terms and definitions

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

2.1 Covid-19 RTK (Self-test)

The COVID-19 RTK (Self-Test) is used as a self-administered screening test. It does not replace the reverse-transcription polymerase chain reaction (RT-PCR) for COVID-19 real-time diagnostic function, but it does have the advantage of determining patient status immediately and conveniently.

3 Requirements

3.1 Evaluation, consideration and conditional approval for an application for this Covid-19 RTK (self-test) will be based on the elements of benefit outweigh risk.

3.2 The conditional approval is valid for one (1) year, and during that time, the establishment is responsible for collecting data on safety and performance, monitor the use as well as be responsible for post-market surveillance and vigilance involving these medical devices.

3.3 After conditional approval is obtained, the establishment shall submit clinical performance studies to MDA to ensure continuous safety and performance of the medical device.

3.4 If there are concerns with the device safety and/or establishment's non-compliance with the requirements of this conditional approval, the given conditional approval may be revoked.

3.5 Establishments applying for conditional approval shall have a valid MDA establishment license with in-vitro diagnostic (IVD) scope on the Good Distribution Practice of Medical Device (GDPMD) certification.

3.6 Establishments shall comply with the labelling requirements stipulated in the Sixth schedule of Medical Devices Regulations 2012 which include instructions for use, methods of reporting to medical practitioners or healthcare facilities (if a positive result/ negative result/ invalid result is obtained), and disposal methods. The establishment shall infographics for effective user comprehension.

3.7 The COVID-19 RTK (self-test) kit granted conditional approval shall only be sold by registered Pharmacies and healthcare institutions registered with Cawangan Kawalan Amalan Perubatan Swasta (CKAPS).

3.8 Online sales are only allowed for registered pharmacies and health institutions and by abiding with the manufacturer's instructions relating to storage and delivery conditions.

3.9 Establishments shall ensure appropriate methods are established such that pharmacies and healthcare institutions selling these self-test kits maintains a record on the customers details to enable good monitoring by the Authority.

3.10 Establishments shall also ensure that adequate explanation is given to customers at the point of sale on the instructions for use, safe disposal and method of reporting if the result turns out to be positive. The use of media is strongly encouraged for this purpose.

3.11 The establishment is responsible for all post-market obligations for medical devices that have been granted conditional approval as stipulated in the Medical Device (Duties and Obligations of Establishments) Regulations 2019.

4 Application procedure

4.1 Conditional approval application is to be submitted via email at: ca.covid19@mdb.gov.my using the Form A in Annex A.

4.2 Applicant is required to submit completed copies of the following documentation:

a) Letter of Authorization from Foreign Manufacturer with list of devices;
b) Valid quality management system (ISO 13485) certificate;
c) Analytical performance report (analytical sensitivity, analytical specificity, interference and/or other analytical tests);
d) Raw data of clinical performance full report (clinical sensitivity, clinical specificity, method comparison- performance validation (cross table), and layman usability);
e) Medical device labelling, IFU & product brochure, text hyperlink or QR Code link to audiovisual demonstration;
f) Disposal procedure (e.g. by providing disposable bag with disinfectant for the disposal of the test kit, and any other instructions for disposal);
g) Methods of reporting self-test Covid-19 test result. (Positive, Negative and inconclusive); and
h) Declaration of Conformity (refer guidance document MDA/GD/0025).

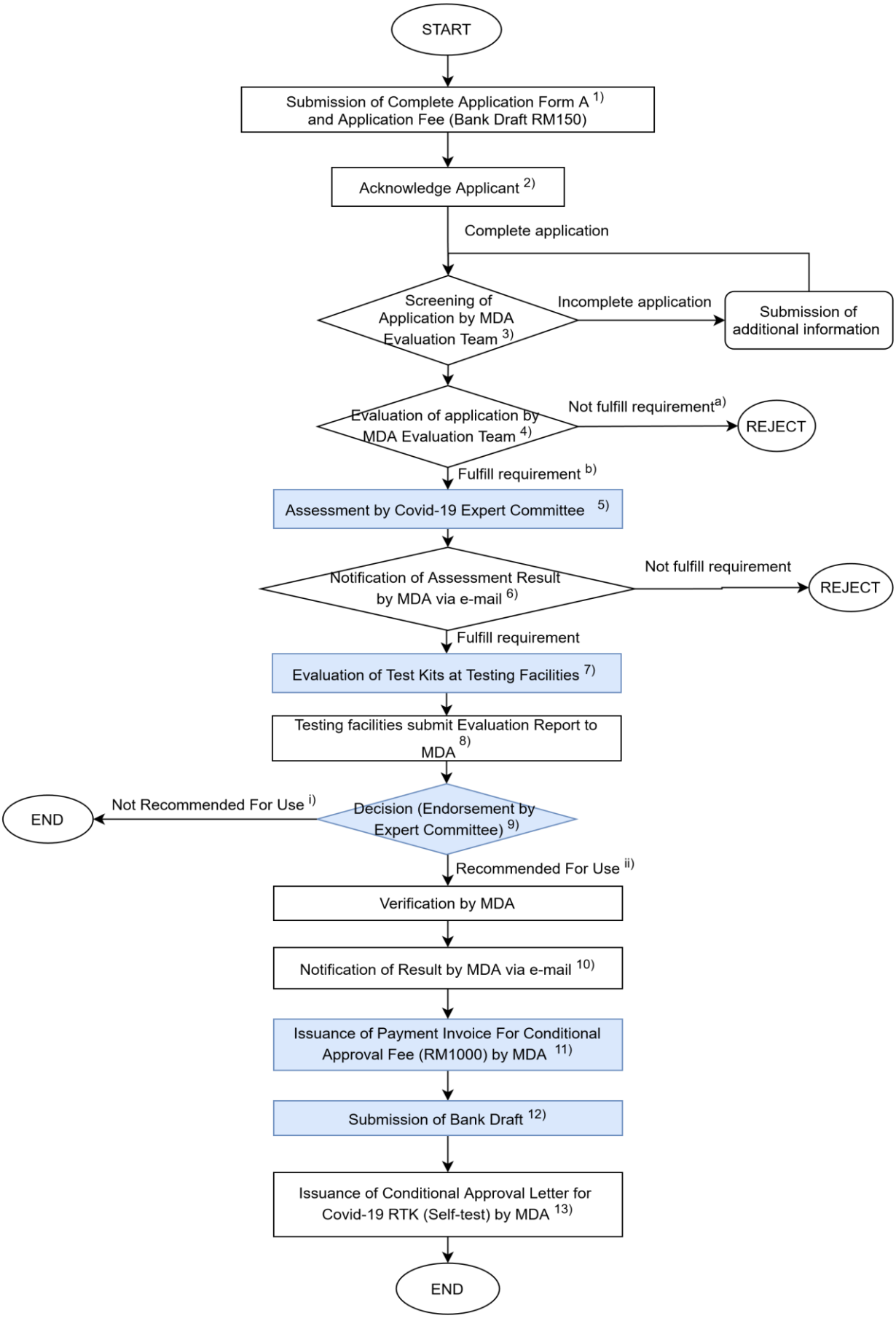
4.3 Submission of evaluation report and Form B in Annex B shall be made by the applicant after receiving the notification of assessment result.

4.4 All application shall be accompanied with a fee as per the table below. Payment of application fee shall be made together with the application and the conditional approval fee prior to receiving the Conditional Approval Letter.

No	Description of fees	Fee Payable (RM)
1	Application Fee	150
2	Conditional Approval Letter Fee	1000

4.5 Approval steps are as per process flow below:

CONDITIONAL APPROVAL FOR COVID19 RTK (SELF-TEST)



4.6 The table below provides explanation on the above flowchart.

Step	Explanatory Notes
1	The applicant shall submit a complete Application Form (Form A) for Conditional Approval for Covid-19 RTK (self-test) together with the Application Fee RM 150 (Bank Draft). *Note: Payment shall be made by Bank Draft to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Please send the hardcopy of Bank Draft together with the form A to MDA.*
2	The Secretariat receiving the application will send an acknowledgement to the applicant.
3	Screening of Application by MDA Evaluation Team and for incomplete applications it will be returned to the applicant for more information/documentation.
4	The application will be evaluated using the Evaluation checklist (CRITERIA CHECKLIST FOR COVID-19 RTK (SELF-TEST) developed by MDA based on WHO and Recognized countries criteria) by the Evaluation team. a) Applications that do not meet the requirements will be rejected. b) Applications that meet the requirements will be moved to the Expert Committee (*Jawatankuasa Pakar Penilaian Akses Khas Covid-19 IVD Test Kit*) Meeting.
5	The expert committee will review the content of each application against the checklist and the test kit that meet the requirements will be assigned to the testing facility.
6	The Applicant will be notified of the Assessment Result for the application that meet the requirements via email together with an Evaluation Letter and Form B.
7	The application that receives the evaluation letter shall go through evaluation testing at the designated assigned testing facility.
8	MDA Evaluation Team will receive Evaluation Report from testing facilities.
9	The test kits that meet the requirements for Recommended for Use will be endorsed during the meeting or by circulation based on the results of the evaluation report. i) Test kits that are not suggested for use will be refused and will not be permitted for usage, with an email notification. ii) Test kits that are recommended for use will be verified by Verification Officer (VO)
10	The applicant will be notified of the decision through email.
11	MDA Evaluation Team will issue a payment advice to the Finance Department (MDA) and the Finance Department will issue an invoice for Conditional Approval fee (RM 1,000) to the applicant.
12	Submission of Bank Draft by applicant to Finance Department. Payment (Conditional Approval Fee) is accepted by the Finance Department, which notifies the Registration Unit.
13	MDA will issue a Conditional Approval Letter for Covid-19 RTK (self-test).

Annex A
(Normative)

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: ca.covid19@mdb.gov.my

APPLICATION FORM FOR CONDITIONAL APPROVAL FOR COVID-19 RTK (SELF TEST) FORM A

All fields are mandatory unless stated otherwise

SECTION A : APPLICANT / COMPANY DETAILS

1. *Please tick the appropriate box:*

Company Establishment License Number and Issuance Date: .....
(Attach copy of Establishment License)

Company's Role :

- ☐ Local Manufacturer
- ☐ Authorized Representative
- ☐ Distributor
- ☐ Importer

1. Name of Applicant:	
2. NRIC No./Passport:	3. Designation:
4. Name & Address of Organization:	
5. Telephone No.:	6. Email Address:

SECTION B: MEDICAL DEVICE DETAILS

Please provide details of the medical device in **Appendix 1.**

APPENDIX 1

MEDICAL DEVICE DETAILS

Name of Medical Device:			
Brief Description:			
Brand:			
Identifier (catalogue or model number):			
Batch/Lot Number:			
Sample Type:			
Intended use of the device:			
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email : 		
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Marketing Approval Status in other country(-ies) (Please : i. state the name (s) of country (ies) ii. provide evidence such as Declaration of Conformity/Device Licence/Registration Certificate/510k/etc) *Provide copy or certificate/license	☐ Registered /Licensed	☐ Exempted/ Notified (eg: EUA Approval)	☐ Others (please specify) ....
GDPMD scope for IVD **(Attach copy of GDPMD certificate)**	.....		

Grouping List :

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description

Note: If more than one (1) medical device, please fill up in a separate sheet

CHECKLIST FOR SUBMISSION

☐ **Complete application form**

☐ **Letter of Authorization from Foreign Manufacturer with list of devices**

☐ **Quality Management System Certificate, ISO13485**

☐ **Analytical Performance**
- Analytical Sensitivity
- Analytical Specificity
- Interference
- Other Analytical tests

☐ **Clinical Performance Report**
- **Clinical Sensitivity**
- **Clinical Specificity**
- **Method Comparison- Performance Validation (Cross table)**
  -The clinical performance of the Covid-19 RTK (self-test) by patient self-testing, and professional testing after supervised self-collection or professional collection.
  -Cross table for the method comparison of Covid-19 RTK (self-test) against RT-PCR
- **Layman usability**

*Provide raw data of Full Report

☐ **Medical device labelling, IFU & Product brochure**
- **Link to audiovisual demonstration**

☐ **Disposal Procedure**
- Provide disposable bag with biohazard symbol and disinfectant for the disposable of the test kit (compulsory)
  *the disposable bag must fit for all materials provided
- Instruction for disposable.

☐ **Reporting Covid-19 Result Method**
- Methods of reporting to medical practitioners or healthcare facilities (if a positive result/ negative result/ invalid result is obtained)

☐ **Declaration of Conformity**

☐ **RM150 Bank Draft payable to 'KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN'**

Note: Payment shall be made by Bank Draft to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN".
Please bring this together with the form A to our address shown above.

For Office Use Only **Acknowledgment of Receipt**

Date of Receipt: : _____
Application Ref. No.: : _____
Applicant's Name: : _____
Company Name: : _____
Payment Status: : **Bank Draft No** :
Application Status: : _____

Acknowledged by: : _____
Officer's Name: : _____
Designation: : _____
Date: : _____

Annex B
(Normative)

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: ca.covid19@mdb.gov.my

APPLICATION FORM FOR CONDITIONAL APPROVAL FOR COVID-19 RTK (SELF TEST) FORM B

All field are mandatory unless stated otherwise

SECTION A : APPLICANT / COMPANY DETAILS

1. Name of Applicant:	
2. NRIC No./Passport:	3. Designation:
4. Name & Address of Organization:	
5. Telephone No.:	6. Email Address:

SECTION B: MEDICAL DEVICE DETAILS

Please provide details of the medical device in **Appendix 1.**

APPENDIX 1

MEDICAL DEVICE DETAILS

Name of Medical Device:	
Brief Description:	
Brand:	
Identifier (catalogue or model number):	
Batch/Lot Number:	
Sample Type:	
Intended use of the device:	
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email:

Grouping List :

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description

Note: If more than one (1) medical device, please fill up in a separate sheet

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:mda.gov.my