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PLACEMENT OF HIV SELF-TEST (HIVST) KIT IN MALAYSIA MARKET

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. However, this guidance document is open for comment and any relevant comment received will be brought to attention for the betterment of this guidance document.

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

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 also serves as guidance for establishments who wish to import, export or place Human Immunodeficiency Virus Self-Test kit (HIVST) in Malaysia market.

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) The Medical Device (Advertising) Regulations 2019;
d) The Medical Device (Duties and Obligations of Establishments) Regulations 2019; and
e) Circular Letter of the Medical Device Authority No.1 Year 2023 *Permission for Placement in the Market of Human Immunodeficiency Virus (HIV) Disease Self-Test Kits.*

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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Abbreviation and Acronyms

CSDT	Common Submission Dossier Template
GDPMD	Good Distribution Practice for Medical Devices
IFU	Instructions for Use
IVD	In-Vitro Diagnostic
MDA	Medical Device Authority
MDR 2012	Medical Device Regulations 2012
NGO	Non-Governmental Organisation
QMS	Quality Management System
QR code	Quick Response code
RFU	Recommended for Use

PLACEMENT OF HIV SELF-TEST (HIVST) KIT IN MALAYSIA MARKET

1 Introduction

Human immunodeficiency virus (HIV) is a retrovirus that targets immune system cells[1] (mainly CD4-positive T-cells and macrophages), making an individual more susceptible to various illnesses and infections. It is transmitted through sharing injection equipment or through direct contact with the bodily fluids of an infected individual. It most frequently happens during unprotected sex (sex without using a condom or HIV medication to prevent or treat HIV).

With 40.1 million cases reported to date, HIV continues to be a severe problem to worldwide public health. Additionally, 650,000 individuals passed away in 2021 from HIV-related causes, and 1.5 million people contracted the virus[2]. This data has warned us, especially the diagnostic health sector, to find the best solution to solve the current issue.

World Health Organization (WHO) has introduced HIV self-testing as an approach to reach people who may not test otherwise, including people from key populations, men and young people[3]. HIV self-testing could be done by introducing **HIV self-test (HIVST)** kits in the in-vitro diagnostic market. This emerging technology could be used as an effective method for controlling HIV risk transmission, which could later help initiate the Pre-exposure prophylaxis (PrEP) programme for the high-risk infected person[4,5].

Detection method for HIVST

i. Type of test

a) Antibody Test

Antibody tests is done to detect for HIV antibodies in a person's blood or oral fluids. Antibody tests can take 23 to 90 days to detect HIV after exposure. The most rapid test and the only FDA-approved HIVST is the antibody test (HIV-1 antibody, HIV-2 antibody). Antibody tests using venous blood can generally detect HIV sooner after infection than tests using fingertip blood or oral fluids[6].

b) Antigen/Antibody Test

The antigen/antibody test is done to detect for both HIV antibodies (HIV-1 antibody, HIV-2 antibody) and antigens (p24 antigen). Antibodies are produced by a person's immune system upon exposure to viruses such as HIV. Antigens are foreign substances that activate a person's immune system. When a person is infected with HIV, an antigen called p24 is produced before antibodies are produced. Antigen/antibody testing is recommended for laboratory testing and is common in the United States. Laboratory antigen/antibody tests on intravenous blood can usually detect HIV 18 to 45 days after exposure. There is also a rapid antigen/antibody test that can be done at your fingertips.

Antigen/antibody tests performed on fingertip blood can take 18 to 90 days after exposure[6].

ii. Type of Sample

Whole blood or Oral fluids

HIVST specifically refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts[7].

2 Scope and application

This document is written to guide the establishment on both pre-market, placement on the market and post-market requirements including requirements on registration of HIVST, licensing of establishments dealing with HIVST, product labelling, advertising and distribution and post-market surveillance and vigilance activities.

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 Human Immunodeficiency Virus (HIV)

An infection that attacks the body's immune system. Acquired immunodeficiency syndrome (AIDS) is the most advanced stage of the disease. (WHO)

3.2 conformity assessment

Technical term given to the process of evaluation and evidence generated and procedures undertaken by the manufacturer, under the requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to essential principles of safety and performance for medical devices

3.3 Conformity Assessment Body (CAB)

The conformity assessment body registered under Section 12 of Act 737.

3.4 recognized countries

Recognized foreign regulatory authorities and notified bodies as stated in MDA Circular Letter No. 2/2014: Conformity Assessment Procedures for Medical Device Approved by Recognized Countries.

4 Establishment Licensing

Establishment dealing with HIVST shall apply for MDA establishment license under Section 15(1) of Act 737 before it can import, export or place in the market the medical device.

Manufacturer for HIVST shall have a valid establishment license with in-vitro diagnostic (IVD) scope on ISO 13485 Medical Device Quality Management Systems.

Authorised Representative (AR), Importer and Distributor for HIVST shall have a valid establishment license with in-vitro diagnostic (IVD) scope on the Good Distribution Practice of Medical Device (GDPMD) certification

Establishment may refer Guidance Documents on Licensing for Establishment MDA/GD/0027 for further information on applying for establishment licence.

5 Registration process of HIVST

The establishment should identify their scenario and provide the appropriate documentation before proceed with registration process. Scenario A and Scenario B are the two types of scenarios reflecting two different registration process flows.

Scenario A as shown in Figure 1, is for HIVST that **has obtained** premarket approval from recognized countries, while **Scenario B** as shown in Figure 2 is for HIVST that **has NOT obtained** any premarket approval from recognized countries.

The performance criteria of the HIVST kit by using the method of detecting antibodies and antigens are as below:

i. The sensitivity of the HIVST shall not be less than 99.0% for blood samples and not less than 92.0% for saliva samples. The sensitivity of the HIVST kit means the ability of the test kit to detect HIV 1 and 2 antibodies in a sample of a person infected with HIV.

ii. The specificity of the HIVST shall not be less than 99.0% for both blood and saliva samples. The specificity of the HIVST kit means the ability of the test kit to detect the blood of a person who is free of HIV infection.

5.1 Registration process flow for Scenario A

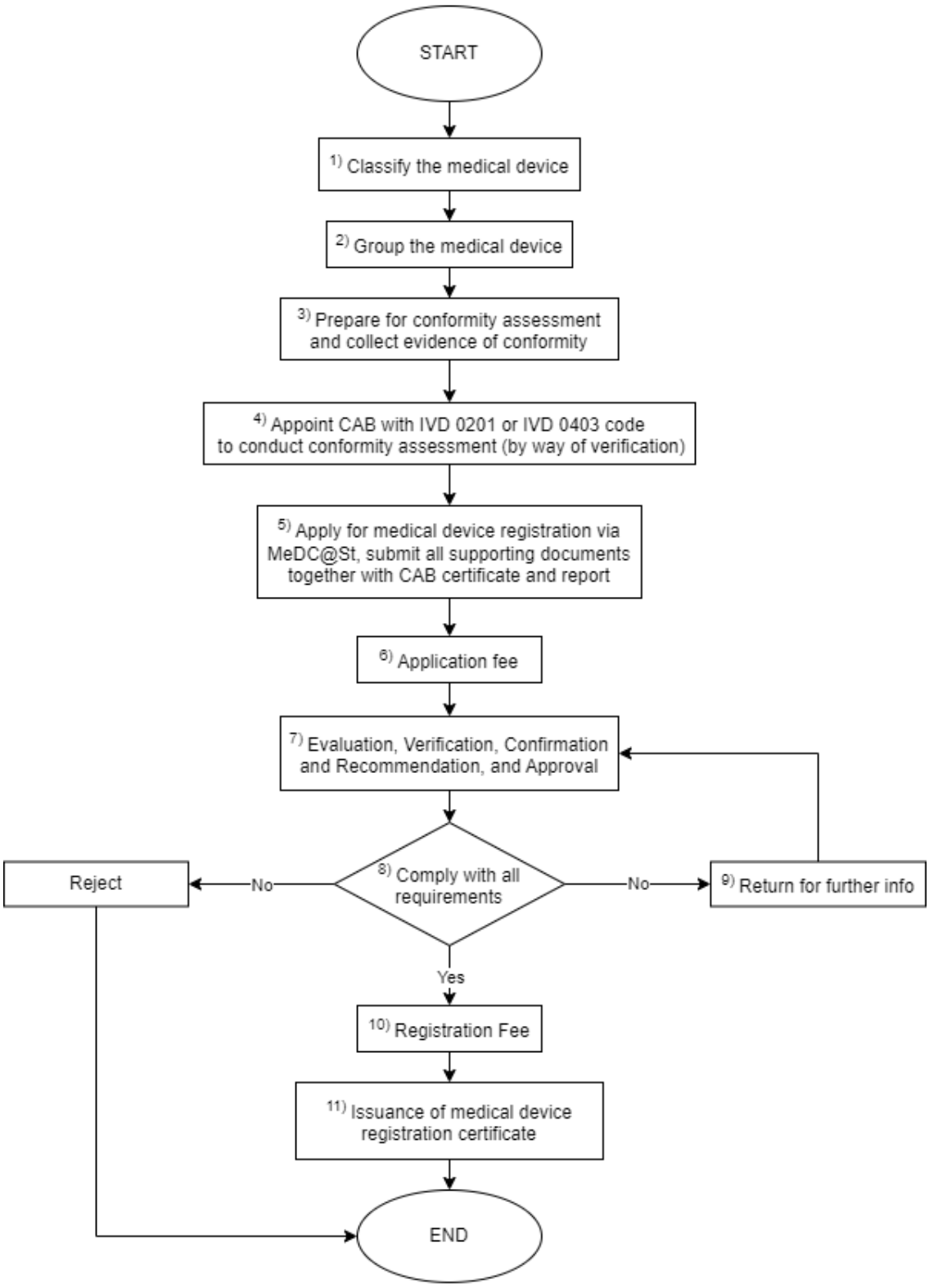

Figure 1: Registration of HIV Self Test kit via MeDC@St for Scenario A

5.1.1 Explanatory notes for Scenario A

Table 1 below describes the registration process of HIVST that has obtained premarket approval from recognized countries, as process flow shown in Figure 1.

Table 1: Explanatory notes for registration application for HIVST that has obtained premarket approval from recognized countries.

No	Step	Explanation
1	Classify and Rule the medical device according to risk classification	The classification and Rule of medical device should be done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001) **Risk Classification for HIVST is Class D, Rule 1**
2	Group the medical device based on grouping criteria	The grouping of medical device should be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on product Grouping for Iv-Vitro Diagnostic (IVD) Medical Device (MDA/GD/0054)
3	Prepare for conformity assessment and collect evidence of conformity	Conformity assessment for the purpose of registration shall comprise of the following elements: i. Quality Management System (QMS) ii. Post-market Surveillance System (PMS) iii. Technical Documentation iv. Declaration of Conformity (DOC)
4	Appoint CAB to conduct conformity assessment	• Engage CAB with Medical Device Technical Areas of IVD 0201 and IVD 0403 code. • CAB to conduct conformity assessment by way of verification according to MDA Circular Letter No. 2/2014: Conformity Assessment Procedures for Medical Device Approved by Recognized Countries • The CAB has to issue certificate of conformity and the report upon completion of the conformity assessment.
5	Apply to register medical device using MeDC@St	• Applicant must create an account before making application via MeDC@St. • Application shall be submitted together with all supporting documents including certificate of conformity and report issued by the CAB.
6,10	Application fee / Registration fee	• The application and registration fee as per Fifth Schedule (Table of Fees) in Medical Device Regulations 2012. • The payment shall be made through bank draft, online banking and credit card.

7	Evaluation, Verification, Confirmation & Recommendation, and Approval Stage	All application will go through Evaluation, Verification, Confirmation & Recommendation, and Approval stage.
8	Comply with all requirement	Comply with the requirements and the information and supporting documents to support the requirement are available.
9	Return for further information	The applicant may receive the application back in the event of: i. Insufficient or unsatisfactory information is provided ii. Supporting document is not attached iii. Wrong supporting document is attached and etc. Note: – Any additional information requested by the Authority need to be furnished and submitted to the Authority via MeDC@St within 90 days from the request date. – The application will be removed from MeDC@St if any additional information requested by the Authority is not provided by the applicant within 90 days or any other extension period allowed by the Authority. However, this will not affect the applicant's right to submit a new application.
11	Issuance of medical device registration certificate	The certificate will be issued once the application has been approved and completed.

5.2 Registration process flow for Scenario B

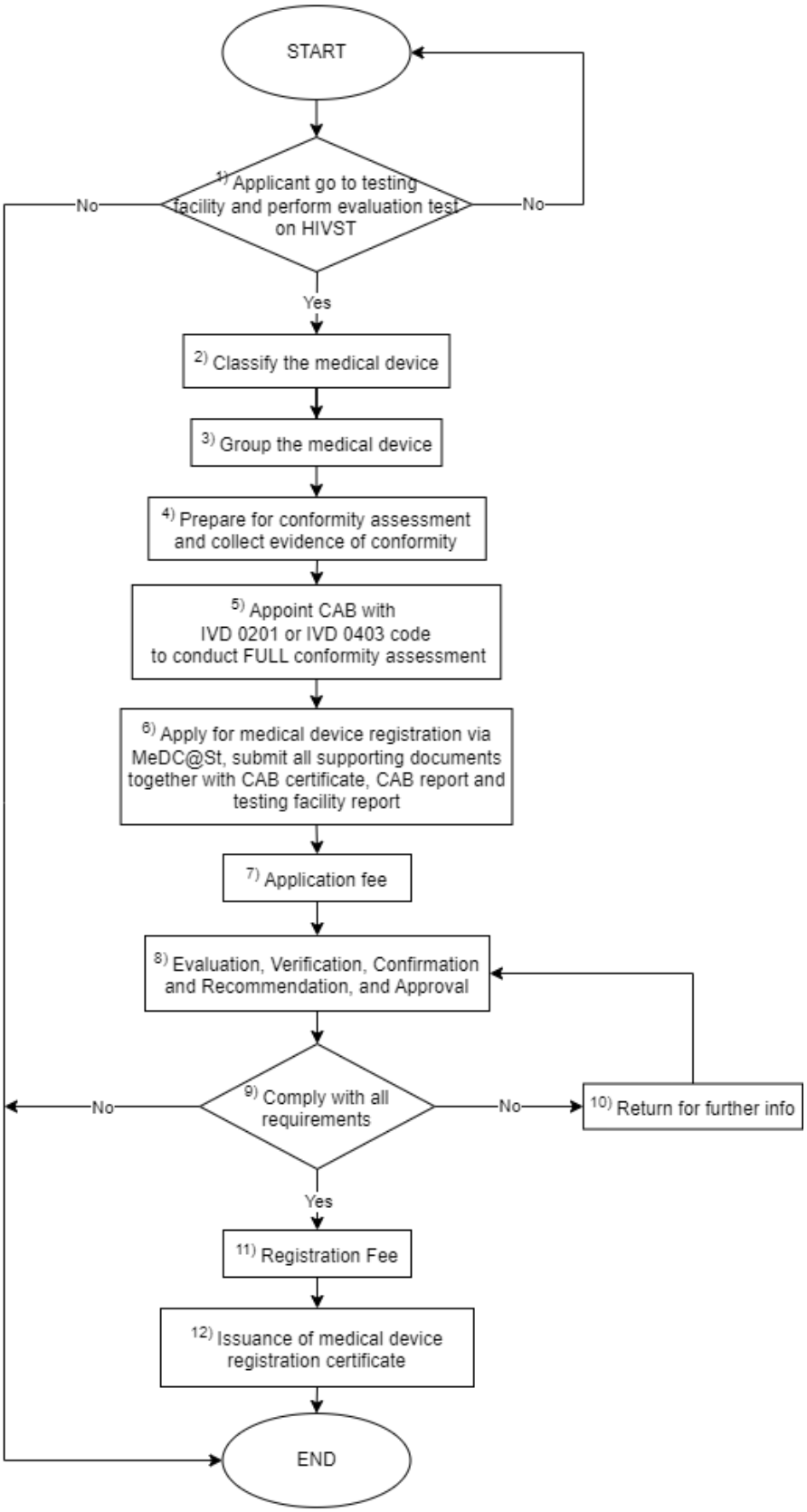

Figure 2: Registration of HIVST kit via MeDC@St for Scenario B (Full Conformity Assessment)

5.2.1 Explanatory notes for Scenario B

Table 2 below describes the registration process of HIVST that has NOT obtained premarket approval from recognized countries, as process flow shown in Figure 2.

Table 2: Explanatory notes for registration application for HIVST that has not obtained any premarket approval from recognized countries.

No	Step	Explanation
1	Applicant perform evaluation test on HIVST at testing facility	Applicant needs to go to testing facility, i.e. Institute Medical Research (IMR) or any accredited local institute/laboratory with ISO 15189, *Medical laboratories - Requirements for quality and competence*. Sensitivity and specificity: a) Whole blood: sensitivity and specificity- ≥ 99% b) Saliva: sensitivity - ≥ 92%, specificity- ≥99%, Notes: – Establishment shall provide about 100 kits (HIVST) for the evaluation process (processing timeline depends on the testing facility) – Report from testing facility will be received by the establishment.
2	Classify and Rule the medical device according to risk classification	The classification and Rule of medical device should be done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001) **Risk Classification for HIVST is Class D, Rule 1**
3	Group the medical device based on grouping criteria	The grouping of medical device should be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on product Grouping for Iv-Vitro Diagnostic (IVD) Medical Device (MDA/GD/0054)
4	Prepare for conformity assessment and collect evidence of conformity	Conformity assessment for the purpose of registration shall comprise of the following elements: i. Quality Management System (QMS) ii. Post-market Surveillance System (PMS) iii. Technical Documentation iv. Declaration of Conformity (DOC)
5	Appoint CAB to conduct conformity assessment	• Engage CAB with Medical Device Technical Areas of IVD 0201 and IVD 0403 code.

		• CAB to conduct FULL conformity assessment according to Third Schedule of Medical Device Regulation 2012: i. the evidence of conformity has to be assessed by the CAB; ii. the CAB shall issue certificate of conformity and report upon completion of the conformity assessment.
6	Apply to register medical device using MeDC@St	• Applicant must create an account before making application via MeDC@St. • Application shall be submitted together with all supporting documents including certificate of conformity and report issued by the CAB.
7,11	Application fee / Registration fee	• The application and registration fee as per Fifth Schedule (Table of Fees) in Medical Device Regulations 2012. • The payment shall be made through bank draft, online banking and credit card.
8	Evaluation, Verification, Confirmation & Recommendation, and Approval Stage	All application will go through Evaluation, Verification, Confirmation & Recommendation, and Approval stage.
9	Comply with all requirement	Comply with the requirements and the information and supporting documents to support the requirement are available.
10	Return for further information	The applicant may receive the application back in the event of: i. Insufficient or unsatisfactory information is provided ii. Supporting document is not attached iii. Wrong supporting document is attached and etc. Note: – Any additional information requested by the Authority need to be furnished and submitted to the Authority via MeDC@St within 90 days from the request date. – The application will be removed from MeDC@St if any additional information requested by the Authority is not provided by the applicant within 90 days or any other extension period allowed by the Authority. However, this will not affect the applicant's right to submit a new application.
12	Issuance of medical device registration certificate	The certificate will be issued once the application has been approved and completed.

5.3 Medical device labelling

The medical device labelling shall be in accordance with requirements in Sixth Schedule of Medical Device Regulation 2012 and the Guidance Documents on Requirements for Labelling of Medical Devices, MDA/GD/0026.

5.3.1 Instruction for use (IFU)

IFU for HIVST shall have;

- IFU date and version
- Statement of “self-test use” in the IFU and product packaging
- English and translation in Bahasa Malaysia
- Infographic and video graphic explanation on how to conduct self-test
- Statement of visit to the TEST NOW platform
- QR code for TEST NOW platform as shown in Figure 4
- Disposal method of HIVST

NOTE:
The TEST NOW platform is an online one-stop centre that provides HIV-related information including HIVST Kits as well as prevention, treatment and referral services. TEST NOW was developed in collaboration between Malaysia AIDS Foundation (MAF) and MOH.

5.3.2 Additional requirements on labelling

i. Video Tutorial

Establishment shall provide audio-visual testing procedure and disposal method by supplying a QR code on the HIVST label.

ii. TEST NOW Platform - Reporting HIV Result Method and further assistance

The HIVST shall be provided with the QR code as in Figure 3 (on label and IFU) in order to allow the user to get further assistance and report the results obtained (positive/negative/invalid) from the test. The statement of visit to the TEST NOW platform is needed to be stated in the IFU as to guide and introduce the user with the TEST NOW platform.

Figure 3: QR Code to TEST NOW Platform

5.4 Other registration requirements

5.4.1 Finger prick needle for HIVST using blood specimen

The finger prick needle that will be supplied in the kit shall be sterile and single use personal lancets and is intended to be used with lancing device (safety lancet) by lay users for finger prick blood sampling as example shown in Figure 4 below.

Figure 4: Examples of single use personal safety lancet

5.4.2 Disposal of used HIVST

Establishment shall provide disposable bag along with the kit and the disposable bag shall fit all materials provided. The IFU shall include information on usage of disposable bag for the disposal of the used test kit.

5.5 Documents to be submitted for HIVST registration

An application for registration of HIVST shall be made to MDA by submitting documents listed in Table 3 below.

Table 3: Required documents for HIVST registration

No	Matters	Remarks (Yes/No)
1	Quality Management System Certificate, ISO13485 of legal manufacturer	
2	GDPMD scope for IVD (Attach copy of GDPMD certificate) – applicable for imported HIVST	
3	Letter of Authorization from Foreign Manufacturer with list of devices - applicable for imported HIVST	
4	Common Submission Dossier Template (CSDT) in accordance with MDR 2012, which contain the following elements:	
	i. Executive summary	
	ii. Essential Principles of Safety and Performance of Medical Devices (EPSP)	

	iii. Description and Test Principle of HIVST Kit • Intended Use (to mention whether professional/self-test use) • Sample type • Instrument (if applicable)	
	iv. List of Configuration (LoC) • Name of HIVST Kit • Identifier • Brand/Model	
	v. Pre-Clinical Studies (Analytical Performance): • Analytical Sensitivity • Analytical Specificity • Interference • Other Analytical tests	
	vi. Clinical Evidence • **Clinical Performance Report** **Please refer to Table 4 for extended requirements for clinical evaluation report.* • **Layman usability report** • **Comparison between self-test VS Professional test report**	
	vii. Medical device labelling, IFU & Product brochure	
	viii. Risk Analysis (according to ISO 14971)	
	ix. Manufacturer Information (Manufacturing process; flowchart)	
5	Certificate and Reports of conformity assessment from CAB, Final evaluation report from testing facility.	
6	Declaration of Conformity (in accordance to the template provided in MDR 2012)	

Table 4: Template of Clinical Evaluation Report

No	Requirement	Notes	
1	Abstract	Summary of overall study	
2	Introduction	A brief description of the study	
3	Overview of detection	A brief description of the detection applicable in this study	
4	Method / clinical trial procedure/ study plan	Study objectives	Type of antigen / antibody
			Sample type (whole blood or saliva)
		Study population	Sample size: Minimum 500 positive and 500 negative samples Whole blood- sensitivity and specificity- ≥ 99% Saliva: sensitivity- ≥ 92%, specificity- ≥99%,
			Inclusion and exclusion criteria
			Location/date of sampling
5	Test kit reagent and/or control kit and/or	Manufacturer	
		Brand	

	equipment and/or sample preservatives	Reference/identifier (if applicable)
		Lot number/Batch number
		Manufacturing date
6	Test principle	The mechanism of the applicable test
7	Test limitation	Description of test limitation
8	Specimen blinding	Blinding, or "masking", is the process by which information that has the potential to influence study results is withheld from one or more parties involved in a research study.
9	Gold standard or Comparator kit information	Manufacturer
		Brand
		Reference/identifier (if applicable)
		Lot number/Batch number
		Manufacturing date
10	Acceptance criteria for evaluation of clinical result	Authenticity evaluation
		Reliability
		Judgemental of clinical result
11	Statistical method and analysis	Calculation for clinical sensitivity and specificity
12	Result and interpretation of result	Cross table for the sensitivity and specificity of HIVST Kit against comparator test kit.
13	Conclusion	Final sensitivity & specificity
14	References	List of bibliography

5.6 Checklist for Conformity Assessment Process by CAB

5.6.1 For Scenario A

HIVST which has obtained premarket approval by regulatory authorities or notified bodies from recognized countries, the conformity assessment by way of verification shall be conducted according to checklist in the MDA Circular Letter No. 2/2014: Conformity Assessment Procedures for Medical Device Approved by Recognized Countries.

5.6.2 For Scenario B

HIVST which has not obtained premarket approval from any recognized countries, full conformity assessment shall be conducted according to Third Schedule of Medical Device Regulation 2012 and checklist in Table 5 below shall be referred to.

Table 5: Checklist for CAB to conduct full conformity assessment

NO.	INFORMATION	COMPLIANCE			EVIDENCE /FINDING
		YES	NO	N/A	
A. CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM					
1	Conformity assessment on Class B, C and D medical devices				
(a)	Establish, maintain and implement a full QMS and appoint CAB to review and conduct on-site audit to verify evidence of conformity to QMS requirements				

(i)	Validity and authenticity of the certificate				
(ii)	Scope of certification is sufficient for the medical device.				
(iii)	Audit report for ISO 13485				
	Note: For establishment that do not already have ISO 13485 certificate, CAB may conduct the certification process and a separate ISO 13485 checklist shall be used.				
B. CONFORMITY ASSESSMENT OF POST-MARKET SURVEILLANCE SYSTEM					
2	Conformity assessment on Class B, C & D medical devices				
(a)	Establish, maintain and implement PMS system				
(b)	Review record and evaluate reports of adverse events.				
(c)	Establish, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall				
(d)	List of reported ongoing incidents globally (if applicable				
(e)	List of incidents that have been resolved for 5 years (if applicable)				
(f)	Date of last audit				
C. CONFORMITY ASSESSMENT OF TECHNICAL DOCUMENTATION					
C.2 Elements of Commission Submission Dossier Template for IVD Medical Device					
16	Executive summary				
(a)	Overview				
	i. medical device description				
	ii. Novel features				
	iii. Synopsis of the content of CSDT				
(b)	Commercial Marketing History				
	i. List of countries where the medical device is marketed, date of introduction to those countries				
(c)	Intended use in its label				
(d)	Indication in its label				
(e)	List of regulatory approval or marketing clearance from other countries with the following information/documents ***Medical devices which have not obtained any approval by regulatory authorities or notified bodies listed in Circular letter**				

	2/2014 is required to undergo full conformity assessment by registered CAB (IVD 0201 & IVD 0403) in accordance with the requirements stipulated in Section 7(1)(a) of Act 737 > Scenario B.				
	i. registration status,				
	ii. intended use,				
	iii. indications				
	iv. copies of certificates/ approvals,				
	v. declaration on label, packaging and IFU				
(f)	Status of any pending application for regulatory approval or marketing clearance				
(g)	Important safety and performance related information:				
	i. summary of reportable adverse events and field corrective actions, If there have not been adverse events of FSCAs to date, an attestation that this is the case required				
(h)	Company stamp, signed by designated person by manufacturer, and dated				
17	Relevant Essential Principles and Method Used to Demonstrate Conformity				
(a)	Determine all the relevant Essential Principle that are applicable to the medical device, taking into account the intended purpose of the device.				
(b)	The specific documents shall be referenced in the element of CSDT to support the rule used to demonstrate conformity to the essential principles				
	i. Compliance with standards according to 5.3.4. Are applicable standards applied in full? (Consider that if standards are referenced on the declaration of conformity, all applicable parts of the standards must be fulfilled)				
	ii. Internal industry methods				
	iii. Comparison to other similar marketed device				
18	Description of medical device;				
(a)	A general description of the principle of assay method or instrument principles of operation.				
(b)	A description of all components of the IVD medical device, including but not limited to:				

	i. antibodies, antigens, nucleic acid primers;				
	ii. buffers, assay controls and calibrators;				
	iii. substrates used to detect antigen-antibody complexes; and				
	iv. reagents provided with the IVD medical device or recommended for use				
(c)	A description of the specimen collection and transport materials provided with the IVD medical device or recommended for use.				
(d)	A description or complete list of various configurations of the IVD medical device to be registered as a family/ system, if applicable. For example, a family of pregnancy rapid test can consist of device available in different configurations, such as a test strip or in a cassette.				
(e)	A description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device. For example, a lancet, which is a medical device and not an IVD medical device that is provided in the package to the user to perform a test. Note: Supporting documents, in CSDT format, must be provided for the medical device accompanying the IVD medical device.				
19	Intended Use				
	i. Type of analyte or measure and of the assay.				
	ii. Whether the test is quantitative or qualitative.				
	iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.				
	iv. Disease or condition that the test is intended for				
	v. Type of specimen to be used e.g. serum, plasma etc.				
	vi. The intended users (e.g. self-testing by lay person, near-patient by trained personnel or professionals				

	vii. Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry				
	viii. The specific name of the instrument required for the assay, if any.				
	ix. For instruments, the intended use shall also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.				
20	Instruction of use				
21	Warnings				
22	Precautions				
23	Materials				
(a)	All components of the IVD medical device shall be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references shall be cited.				
(b)	If synthetic peptides are used, the peptide sequence shall be provided				
(c)	If components are of biological origin or recombinant, the source must be indicated and details on production must be provided. These details would include the strain of the virus, the cell line for cultivation of the virus, sequences of relevant nucleic acids and amino acids, etc., used in the manufacturing process of viral lysate, purified proteins, recombinant and synthetic proteins.				
(d)	If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents. This also includes inactivation of infectious organisms in reagents and the production of reagents.				
(e)	if applicable, information to be provided on irradiating components, nonionising or ionising (e.g. Iodide-131 in the Radioimmunoassay kit, radio-labelled Phosphorus-32 DNA probes in Southern blots)				

(f)	if applicable, information to be provided on the poison or controlled substance (e.g. Buprenorphine in drug assay kit).				
24	Other relevant Specifications				
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.				
25	Other descriptive Information				
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles				
26	Product verification and Validation				
(a)	Pre-clinical Studies The pre-clinical studies provided should include information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions. The most common characteristics that must be validated should include but are not limited to:				
	i. Analytical Sensitivity				
	ii. Analytical Specificity and Interference				
	iii. Precision (Repeatability /Reproducibility)				
	iv. Linearity/Assay's Measuring (Reportable) Range				
	v. Traceability, & Expected Values				
	vi. Cut-off Value				

	vii. Trueness				
	viii. Stability of reagent				
	ix. Specimen stability				
	x. Performance Characteristics for Instrument (if applicable):				
	xi. Accuracy				
	xii. Precision/Reproducibility				
	xiii. Linearity				
	xiv. Carryover				
	xv. Interfering Substances				
	xvi. Projected useful life				
	xvii. Software Verification and Validation Studies				
(b)	Clinical Evidence **(from manufacturer)** The clinical evidence to be provided shall include the information mentioned in this section. For any IVD medical device, if discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, using one or more of the following approaches:-				
	i. evaluation of the discrepant sample in further test systems,				
	ii. use of an alternative method or marker,				
	iii. a review of the clinical status and diagnosis of the patient,				
	iv. the testing of follow-up-samples.				
	v. Clinical (Diagnostic): Whole blood: Sensitivity ≥99%, specificity ≥99% Saliva: Sensitivity ≥ 92%, specificity≥99% Sample sizes: minimum 500 positive and 500 negative				
	vi. Comparison Studies Using Clinical Specimens (Method comparison: All performance evaluations shall be carried out in direct comparison with an established state of the art IVD medical device. The established product for comparison must have obtained marketing clearance from the reference agencies, namely Australia TGA, Canada TPP, Europe, Japan MHLW, and US FDA.				
(c)	Result shall include:-				
	i. Description on the overall results and/or results from specific sites and patient groups, as appropriate				

	ii. For quantitative tests, information such as slope and intercept (with confidence intervals), correlation coefficient, measure of scatter around the regression line, measure of bias at medical decision levels				
	iii. In some cases, a graph (x-y graph or bias plot) can be included, and				
	iv. For qualitative or semi-quantitative tests, per cent agreement with comparator for positive/negative samples, confidence intervals.				
(d)	Matrix comparison:				
	i. for each matrix in the intended use, the method for comparison or determination of accuracy, and				
	ii. sample types tested, number of samples, sample range or target concentrations tested and calculations/statistical methods				
	iii. Results/Acceptance criteria shall include: the accuracy of the new matrix or results of the matrix comparison				
(e)	Clinical Cut-off				
	i. The established cut-off and its validation for the new IVD medical device; and				
	ii. If applicable, the “equivocal zone” is to be defined, and include a description of how results within this zone are reportable to the user				
(f)	Reference Interval (Expected Values)				
	i. The reference interval for this measured and the method used to determine it;				
	ii. Additional requirements for IVD medical device for self-testing and near patient testing (if applicable)				
(g)	USE of Existing Bibliography				
	Final Evaluation Report from testing facility				
a)	Final evaluation report from testing facility: Please state the sensitivity and specificity percentages as well as the type of sample used. Sample sizes: minimum 50 positive and 50 negative				

27	Device labelling				
(a)	Sample of labelling is provided Note: Labelling complies with requirements as per MDA/GD/0026 – guidance Document on requirement for labelling of medical device.				
	i. Labels on the device and its packaging;				
	ii. Instructions for use;				
28	Risk analysis/ Risk Management file				
(a)	Risk management report demonstrated conformance with ISO 14971				
29	Manufacturing Information				
(a)	Documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device. Manufacturing process shall include resources and activities that transform input into the desired output.				
D. DECLARATION OF CONFORMITY					
16	Prepare declaration of conformity as per specified in MDA/GD/0025.				
(a)	Name and address of manufacturer and printed on company letterhead				
(b)	Name of Person Responsible/ Manufacturer				
(c)	Particular of medical device:				
	i. Generic Name				
	ii. Specified Name				
	iii. Brand / Model				
	iv. Manufacturer				
	v. Country of Origin				
	vi. Manufacturing Site				
	vii. Risk-based classification				
	viii. Classification rule				
	ix. GMDN Code				
	x. Medical Device Registration Code/ Approval number (e.g.: CE marking code, USFDA approval number, etc)				
(d)	QMS certificate				
	i. Conformity Assessment Body issuing the certificate				
	ii. Certificate Number				
	iii. Issuance Date				
	iv. Expiry Date				

(e)	List of all standards (vertical and horizontal standard) applicable for the medical device.				
(f)	Name & Position i. The name and position of top management ii. Company Stamp				
(g)	Signature and date of Signatory				

The application for registration shall be made to the Authority through an online, web-based system called — Medical Device Centralized Online Application System (MeDC@St) as per MDA guideline MDA/GL/MD-01 and MDA/GL/IVD-1.

Applicant shall send a sample of HIVST to Medical Device Registration Unit, MDA for physical evaluation of the kit. Please label HIVST with submission ID obtained from MedC@st and pack the kit properly. Please ensure that the information given in the kit's labelling matches with the information given in the MedC@st.

5.7 Evaluation Timeline

The evaluation timeline for the registration of HIVST kit is 30 working days upon the submission of complete documents.

5.8 Table of Fees

As per the Fifth Schedule of the Medical Device Regulations 2012, the descriptions of fees for Class D, Rule 1, devices are as below:

Type of Fee	Fee
Application Fee	RM 750
Registration Fee	RM 3,000

6 HIVST Sales and Distribution Requirements

a) The distribution activities that are allowed to be implemented are as follows:

i. Establishments (authorized representatives or manufacturers) to other establishments (distributors) appointed and licensed;
ii. Establishment to public and private healthcare facilities; and
iii. Establishment to NGOs, specifically for NGOs and its partner organizations that collaborate with the MOH.

b) HIVST can only be sold or supplied to the public by:

i. Community pharmacy licensed with the Pharmacy Services Program, MOH;
ii. Public and private healthcare facilities; and
iii. NGOs and its partner organizations that collaborate with the MOH.

HIVST can only be sold online by b(i) and (iii). However, deliveries shall be carried out by suitable logistic providers with assurance of safety and performance.

c) The sale of HIVST by individuals either physically or online is strictly prohibited.

7 Advertisement requirements

The medical device advertisement shall be in accordance with requirements in Section 44 of Act 737, Medical Device (Advertising) Regulation 2019 and the Code of Advertisement MDA/GD/0032. Establishment may refer to MDA/GL/04 Application for Medical Device Advertisement Approval-Requirement for further information.

8 Post-market Surveillance

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.

The Chapter 3 of the Medical Devices Act 2012 (Act 737) and the Medical Devices (Duties and obligations of establishment) Regulations 2019 provide 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.

Establishments shall also comply with the requirements in 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.

If the establishment finds a failure or deterioration in the effectiveness of the medical device, the establishment shall inform the Authority and make a public announcement in any medium deemed appropriate to convey the information to the public and parties concerned. Refer to www.medcrest.mda.gov.my for post-market reporting.

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MEDICAL DEVICE AUTHORITY

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