ENGAGEMENT WITH IVD ESTABLISHMENTS & SURVEY ON IN-VITRO DIAGNOSTIC ISSUES

Latest updates on IVD registration requirements.

Possible Ways to Register IVD Analyzer

Updated on:
November 2023

Placement Of HIV Self-test (HIVST) Kit In Malaysia Market

Updated on:

19 February 2024

Possible ways of registering IVD staining kits.

Updated on:

22 February 2024

Possible Ways of Registering Microbiological Culture Media

Updated on:

22 February 2024

Update on Covid-19 application registration requirements.

Updated on:

10 Mei 2024

Possible Ways to Register IVD Analyzer

01 IVD Analyzer

Analyzer →

Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures .These instruments are classified as class A, whereas reagents and kits are classified in their own right.

EAXMPLES (non-exhaustive)

- Enzyme immunoassay analyser, PCR thermocycler, microplate reader, clinical chemistry analyser.
- Instrument for automated purification of nucleic acids and automated nucleic acids extractor

Ref: MDCG 2020-16 rev.2

02 Analyzer in combination with the reagents, calibrators, controls, buffer/ washing solutions

Analyzer + Reagent →

Follow class of reagent
For examples:

CLINICAL CHEMISTRY ANALYZER + Reagent assay + Diluent

IMMUNOASSAY ANALYZER-COAGULATION + D-Dimer reagent + D-Dimer control

Ref: MDA/GD/0001

03 Interdependent Analyzer – with condition as below

Analyzer →

If the instrument has an independent measuring function which does not use any additional reagents, it is classified according to the intended purpose of the analysis (including instruments controls or instrument quality control).

Example: cell counting analyzers used in haematology, ion selective electrodes, instruments measuring blood gases or glucose via its sensors, specific gravity measurements in urine analysis, mass spectrophotometer for bacteria identification, erythrocyte sedimentation rate analyser etc.

Ref: MDCG 2020-16 rev.2

Remark: For any inquiry please email to ivd.registration@mda.gov.my

Updated: November 2023

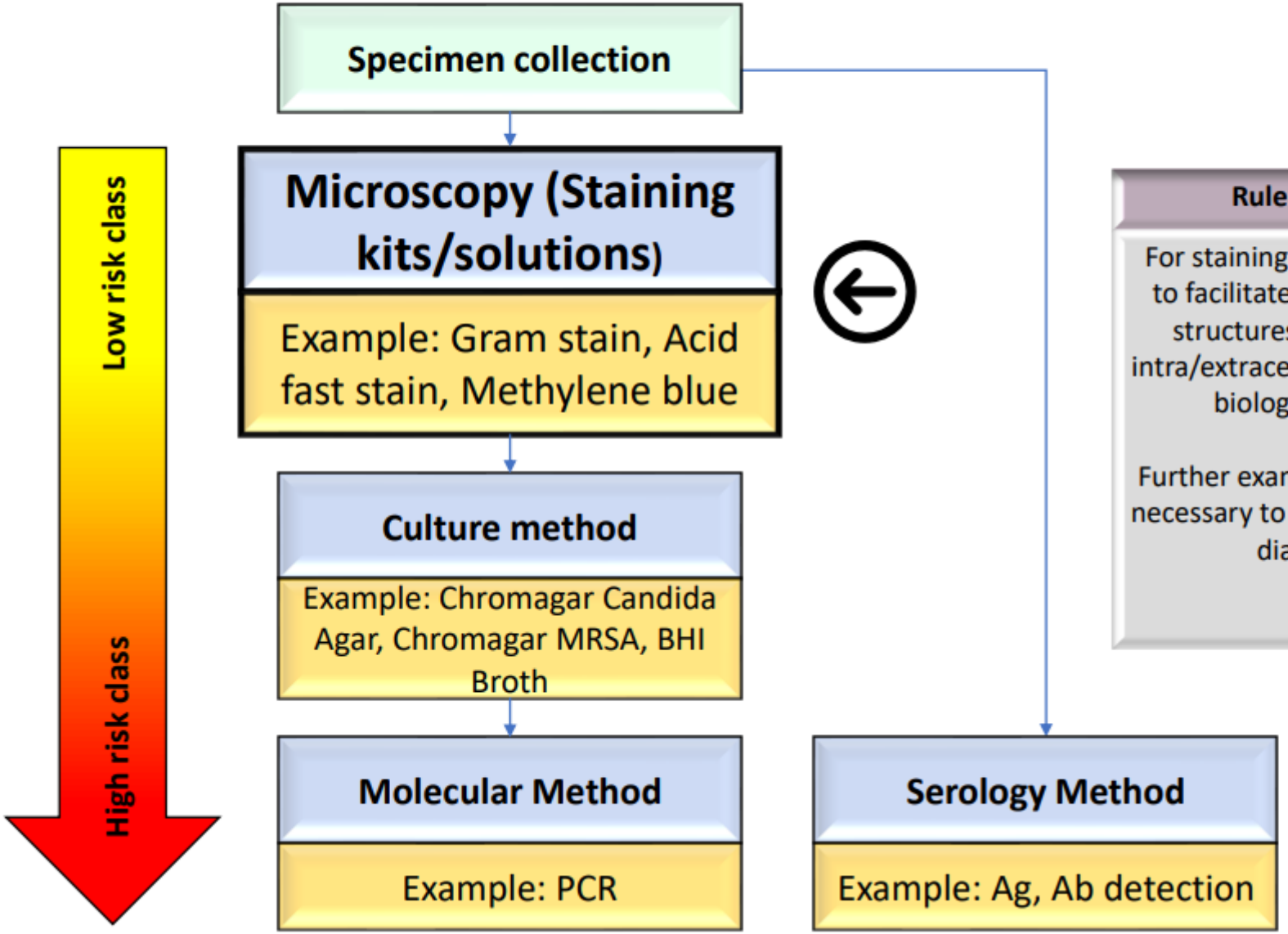
1. **Analyzer only/ without reagents** = **Class A**

2. **Analyzer**
Ex: Clinical Chemistry analyzer
+ **Reagent**
Ex: reagent assay + diluent
= **Follow Class Reagent**
*Class B/C/D

3. **Independent Measuring function Analyzer**
Ex: ESR analyzer
+ *with/without **Sample (Collection tube)**
Ex: Blood (Black Top Tube (Vac-Tec)
= **Follow intended purpose of analysis**
Ex: Class B

* Note: Sample (collection tube) not compulsory to be included to determine the classification for registration. It just for example to explain on possible ways for analyser focus for independent analyser.

Possible ways of registering IVD staining kits

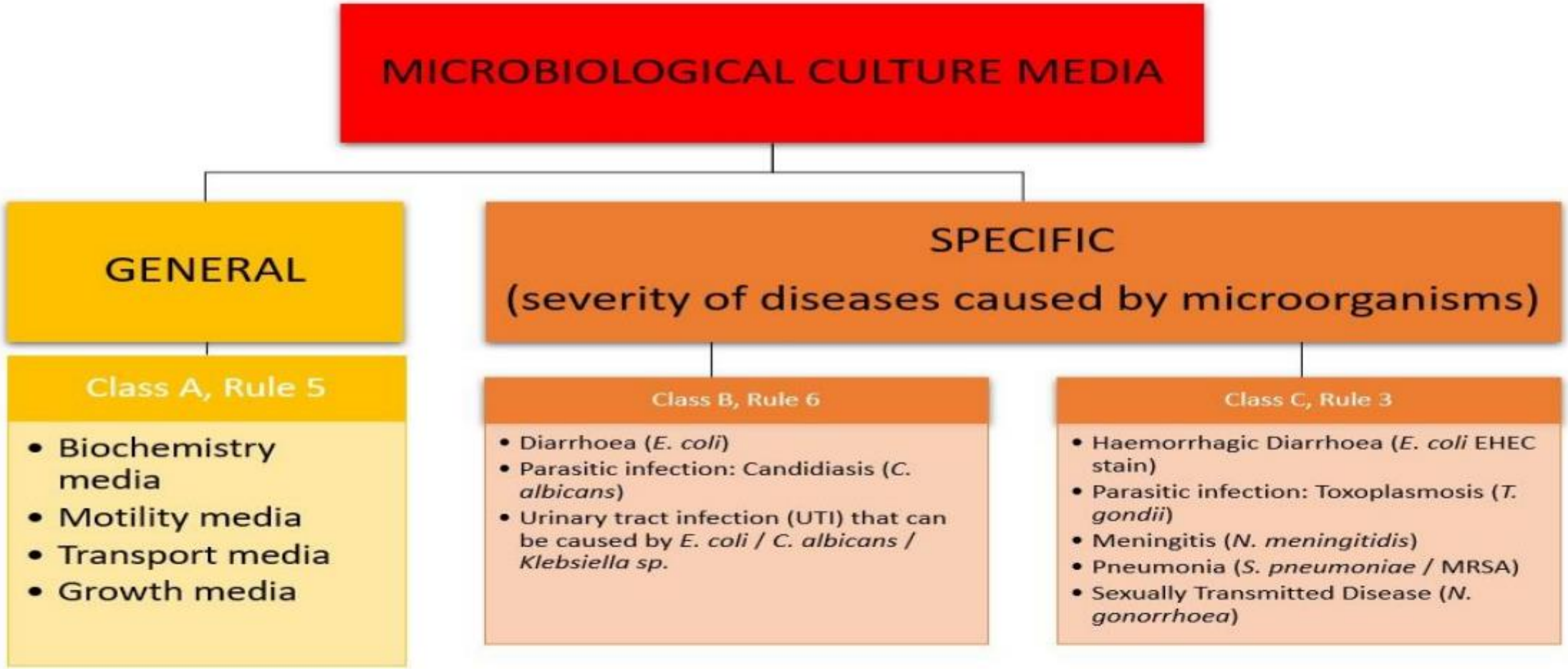


PLEASE TAKE NOTE:

Rule 5 Class A	Rule 6 Class B/Rule 3 Class C
For staining microorganisms to facilitate visualization of structures and/or other intra/extracellular elements in biological tissues Further examinations may be necessary to reach a definitive diagnosis.	Immunohistochemistry (IHC) staining classification is Class B or C Rationale: IHC is used to detect the presence of specific protein markers that can assist with accurate tumor classification and diagnosis.

Updated: 22/2/2024

Possible Ways of Registering Microbiological Culture Media



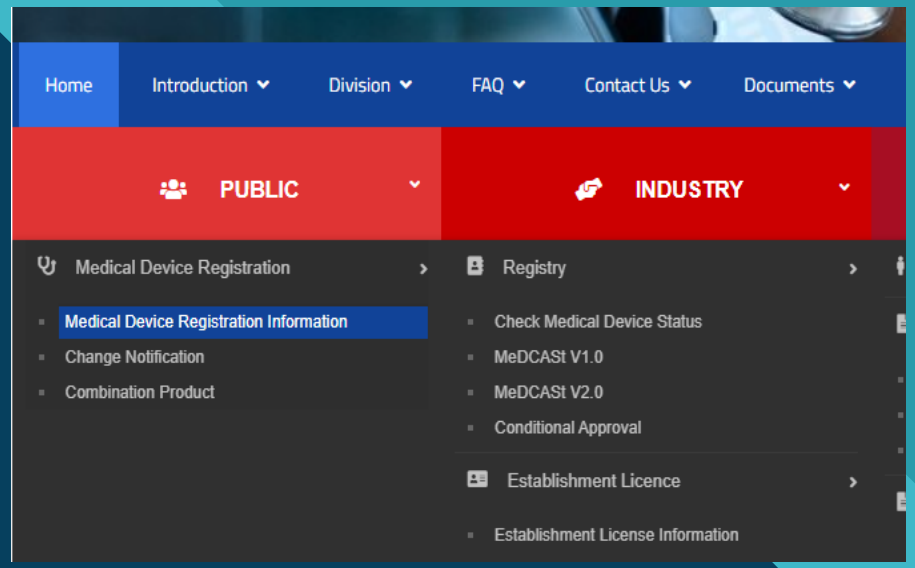
Notes:

*Examples given above considered as non-exhaustive.

*Classification of microbiological media can be based on the intended use & type of the microbiological media (i.e. general or specific), on microorganisms and severity of the diseases causes by the microorganisms.

Updated 22/2/2024

New information and announcement in MDA Portal (https://www.mda.gov.my)



9. Information on Fee Structure for Medical Device Registration

10. Classification and Registration Technical Committee Meeting

a. 2024 Meeting Schedule Planner
b. 2023 Meeting Decision
   i. Aug 2023 - Implementation requirements on quality management system (QMS) and traceability form
   ii. Nov 2023 - Possible ways to register IVD analyser
   iii. List of medical device risk classification
   iv. List of products (medical device or non-medical device)
c. 2024 Meeting Decision
   i. February 2024
      - Possible ways of registering IVD staining kits
      - Possible ways of registering Microbiological Culture Media

MoH Guidelines HIV Self-screening Test (HIVST) medical devices

- MoH just released Guidelines HIV Self-screening Test In Malaysia.

----The guidelines explain the program's implementation requirements, objectives, target groups, test kit criteria and standards, as well as procedures for performing HIV self-tests.

- Risk Classification for HIV self-screening Test (HIVST) will be Class D, Rule 1

Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil 14/2023

KETUA PENGARAH KESIHATAN MALAYSIA
Kementerian Kesihatan Malaysia
Aras 12, Blok E7, Kompleks E,
Pusat Pentadbiran Kerajaan Persekutuan
62590 PUTRAJAYA

Tel.: 03-8000 8000
Faks: 03-8889 5542

Rujukan Tuan :
Rujukan Kami : KKM.500-28/3/3 JLD 3 (14)
Tarikh : 14 Ogos 2023

SEPERTI SENARAI EDARAN

YBhg. Datuk /Dato' Indera /Datin Paduka /Dato' /Datin /Tuan /Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL. 14 /2023 : GARIS PANDUAN PELAKSANAAN UJIAN SARINGAN HIV KENDIRI DI MALAYSIA

1. TUJUAN

Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil. 14/2023 ini bertujuan untuk menerangkan dasar dan garis panduan pelaksanaan ujian saringan HIV kendiri di Malaysia.

2. LATAR BELAKANG

2.1 Pengesanan melalui ujian saringan merupakan langkah utama untuk mengurangkan penularan kes HIV baru. Pelaksanaan ujian saringan HIV kendiri telah diperakui di peringkat antarabangsa dan disarankan oleh Pertubuhan Kesihatan Sedunia (WHO) semenjak tahun 2016 melalui *Consolidated Guidelines on HIV testing services*.

2.2 Selari dengan saranan WHO ini, pelaksanaan ujian saringan HIV kendiri di Malaysia bertujuan untuk meningkatkan akses ujian HIV kepada golongan berisiko tinggi khususnya golongan muda dan pasangan mereka disamping merupakan opsyen tambahan kepada perkhidmatan ujian saringan HIV yang sedia ada.

MDA GUIDANCE DOCUMENT FOR PLACING HIV SELF-TEST (HIVST) KIT IN MALAYSIA MARKET (MDA/GD/0065)

- **Scenario A**, is for HIVST that has obtained premarket approval from recognized countries,.

  -conduct conformity assessment by way of verification according to MDA Circular Letter No. 2/2014

- **Scenario B** is for HIVST that has NOT obtained any premarket approval from recognized countries.

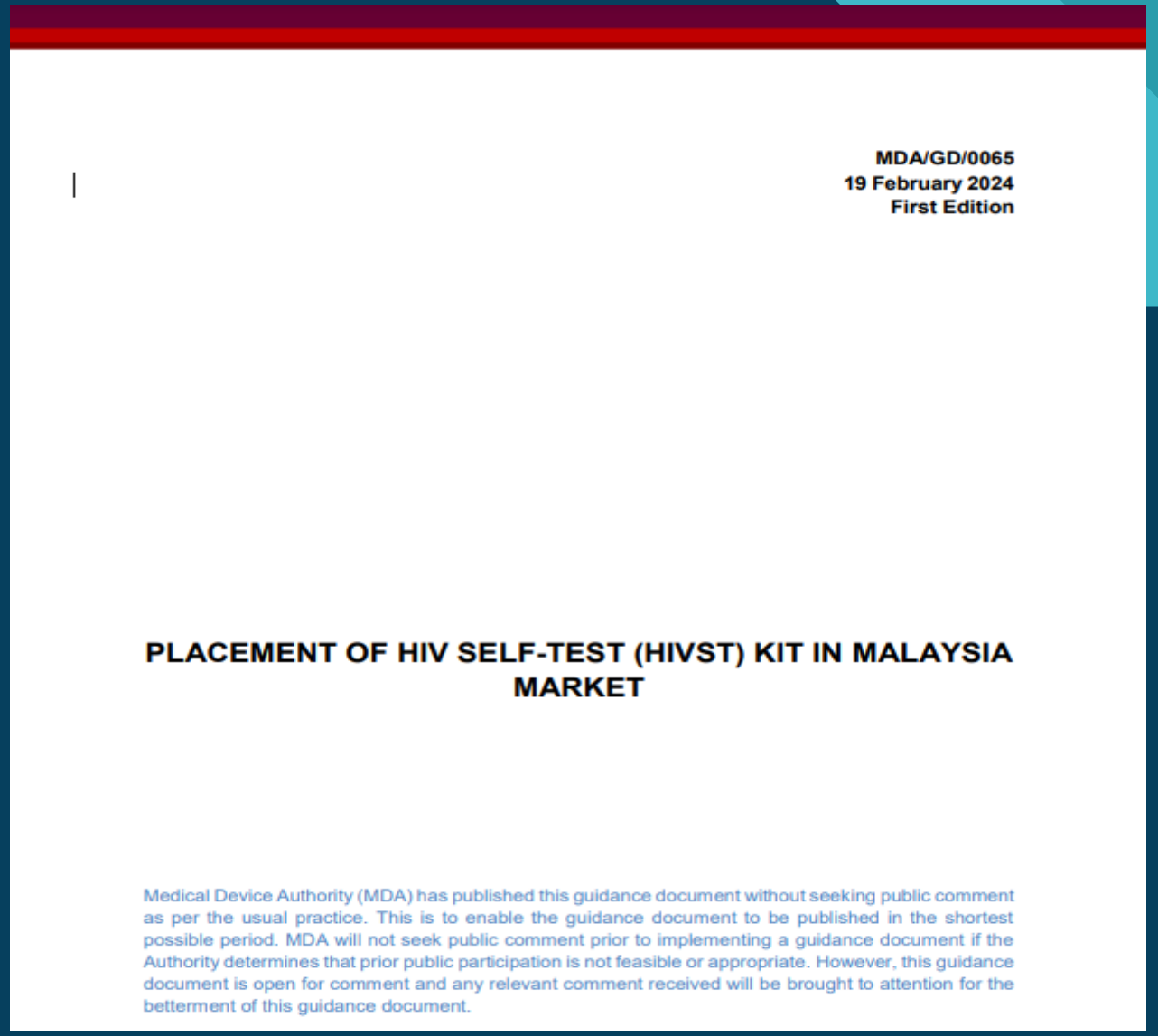
  -Applicant needs to go to testing facility for performance test,

  i.e. Institute Medical Research (IMR) or any accredited local institute/laboratory

  -conduct FULL conformity assessment according to Third Schedule of Medical Device Regulation 2012

- CAB with **IVD 0201 and IVD 0403** code.

Placement Of HIV Self-test (HIVST) Kit In Malaysia Market

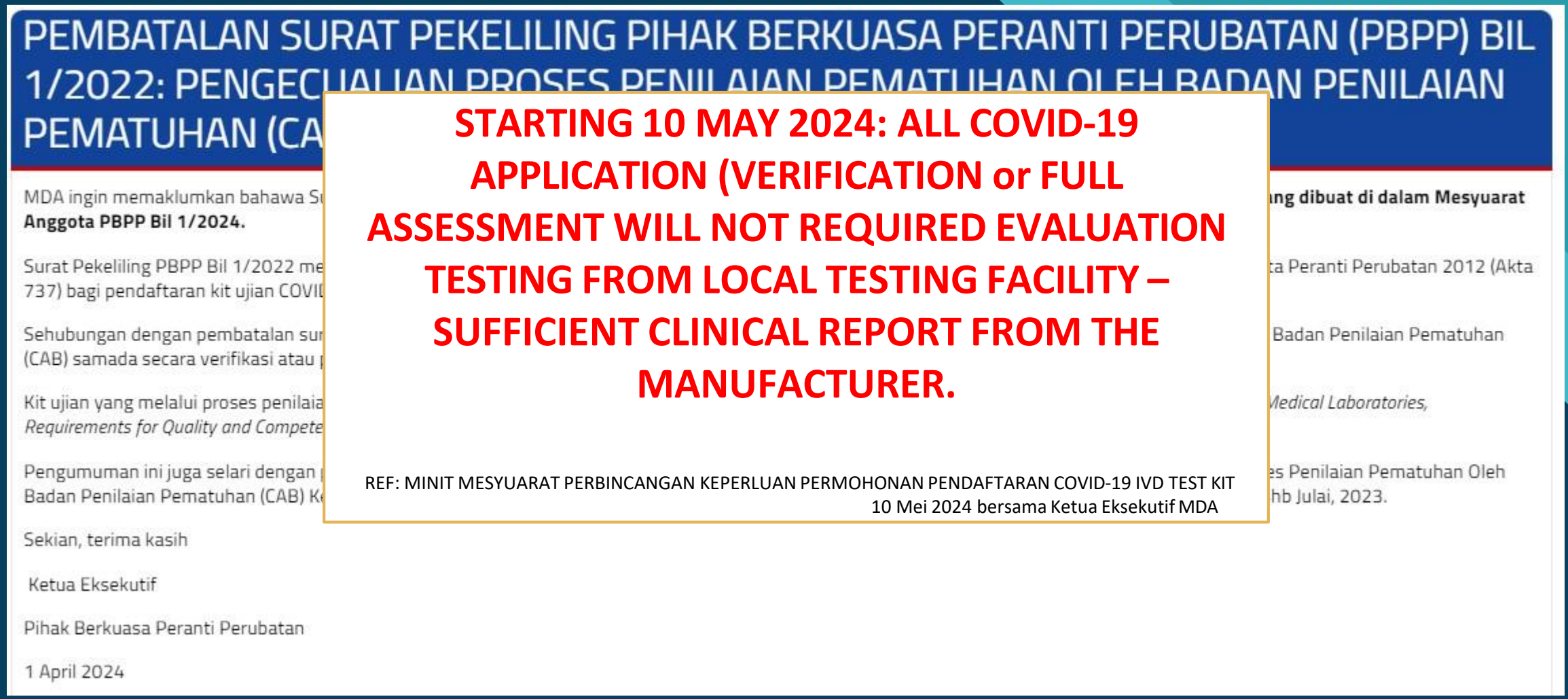


MDA/GD/0065
19 February 2024
First Edition

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.

Update on Covid-19 application registration requirements.
Updated : 10 Mei 2024



PEMBATALAN SURAT PEKELILING PIHAK BERKUASA PERANTI PERUBATAN (PBPP) BIL 1/2022: PENGEC[illegible] PEMATUHAN (CA[illegible]

MDA ingin memaklumkan bahawa S[illegible] **Anggota PBPP Bil 1/2024.**

Surat Pekeliling PBPP Bil 1/2022 me[illegible] 737) bagi pendaftaran kit ujian COVI[illegible]

Sehubungan dengan pembatalan sur[illegible] (CAB) samada secara verifikasi atau [illegible]

Kit ujian yang melalui proses penilaia[illegible] *Requirements for Quality and Compete[illegible]*

Pengumuman ini juga selari dengan [illegible] Badan Penilaian Pematuhan (CAB) K[illegible]

Sekian, terima kasih

Ketua Eksekutif

Pihak Berkuasa Peranti Perubatan

1 April 2024

STARTING 10 MAY 2024: ALL COVID-19 APPLICATION (VERIFICATION or FULL ASSESSMENT WILL NOT REQUIRED EVALUATION TESTING FROM LOCAL TESTING FACILITY – SUFFICIENT CLINICAL REPORT FROM THE MANUFACTURER.

REF: MINIT MESYUARAT PERBINCANGAN KEPERLUAN PERMOHONAN PENDAFTARAN COVID-19 IVD TEST KIT 10 Mei 2024 bersama Ketua Eksekutif MDA

A new announcement will be uploaded in MDA website – The details will be further elaborate in the announcement. Please be vigilance to our MDA Portal for updates.

https://portal.mda.gov.my/index.php/industry/medical-device-registration/medical-device-registration-information

RECAP

PRE-MARKET MEDICAL DEVICE REGISTRATION (IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE)			
Title	**Code**	**Version Number**	**Published Date**
Definition of Medical Device	MDA/GD/0006	First Edition	March 2014
In-Vitro Diagnostic (IVD) Medical Device Classification System	MDA/GD/0001	Second Edition	December 2020
Product Grouping for IVD	MDA/GD/0054	Second Edition	January 2021
Requirements of Labelling for Medical Devices	MDA/GD/0026	Sixth Edition	21 November 2022
Essential Principles of Safety and Performance for IVD Medical Device	MDA/GD/0002	First Edition	July 2013
Common Submission Dossier Template (CSDT) of IVD Medical Device	MDA/GD/0004	First Edition	July 2013
Declaration of Conformity (DOC)	MDA/GD/0025	First Edition	February 2016
Change Notification for Registered Medical Device	MDA/GD/0020	Fourth Edition	21 November 2022
Guideline on How to Apply for Apply for In-Vitro Diagnostic (IVD) the Medical Device Registration under Act 737	MDA/GL No. 2		
Medical Device Specific Requirements			
Placement Of HIV Self-Test (HIVST) Kit In Malaysia Market	MDA/GD/0065	First Edition	19 February 2024

THANK YOU

Any inquiries, kindly email to:

Email Address:

ivd.registration@mda.gov.my

Registration Unit .: 03-8230 0376