



Our Ref : (55) dlm. MDA. 100-1/7/2

Date : 14th July 2021

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 1 YEAR 2021**

**POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL
DEVICE ACT 2012 (ACT 737):**

**PERMISSION FOR IMPORTATION AND DISTRIBUTION OF
COVID-19 SELF-TEST KITS**

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) relating Conditional Approval for COVID-19 self-test kits.

BACKGROUND

2) Since the outbreak of COVID-19 in Malaysia, MDA has taken the approach of granting temporary permission through special access notifications to suppliers wishing to supply COVID-19 test kits.

3) Special access notifications are made pursuant to the Medical Devices (Exemptions) Order 2016 (P.U. (A) 103) which exempts any medical device for the use by medical practitioners in emergency situations from the registration and licensing requirements stipulated under Sections 5 and 15 of Act 737.

4) However, the COVID-19 self-test kit cannot be granted through special access notification as the requirement states that the medical device shall be operated by a medical practitioner and the applicant shall provide the information on medical practitioner and facilities requires the medical device.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

5) **The Medical Devices Authority has decided to set the policy for implementation and enforcement for the exemption of the medical device registration requirement under Section 5 of Act 737 on COVID-19 self-test kit, by granting Conditional Approval for the importation and distribution of COVID-19 self-test kit and shall comply with the requirements with certain fees as specified by the Authority.**

6) This exemption is implemented administratively before order is published in the Gazette.

USAGE AND EFFECTIVE DATE

7) Circular issued shall be used as part of requirements under Act 737 and this circular shall be effective from the date it is issued.

ENQUIRIES

8) Any enquiries relating to this circular can be forwarded to:

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran Apec,
63000 Cyberjaya, Selangor, MALAYSIA
Tel: (+603) 8230 0300, Fax: (+603) 8230 0200
Emel: mdb@mda.gov.my

Thank you.

"PRIHATIN RAKYAT: DARURAT MEMERANGI COVID-19"

"BERKHIDMAT UNTUK NEGARA"



(TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia