PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

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

OBSOLETE

Date : 9 May 2022

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 1 YEAR 2022

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

EXEMPTION FROM THE CONFORMITY ASSESSMENT PROCESS BY THE CONFORMITY ASSESSMENT BODY (CAB) FOR REGISTRATION OF COVID-19 TEST KIT

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Act 737 to exempt conformity assessment process by the Conformity Assessment Body (CAB) for registration of COVID-19 test kits.

BACKGROUND

2) Section 5 (1) of Act 737 states that all medical devices shall be registered before they can be imported, exported or placed on the market. Section 7 (1) (a) states that a medical device shall undergo a conformity assessment procedure conducted by the CAB before it can be registered.

3) 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. Special access notifications are made pursuant to the Medical Devices (Exemptions) Order 2016 (P.U. (A) 103).

4) For COVID-19 self-test kit, a policy has been set to grant Conditional Approval for the importation and distribution of self-test kit starting 14 July 2021.

5) Considering the current situation, starting 1st of February 2022, COVID-19 test kits for both self-test and professional use shall be registered under Section 5 of Act 737 before being placed on the market. However, there were difficulties faced by the establishment to go through the conformity assessment process conducted by the CAB for the registration of the COVID-19 test kit.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Devices Authority Meeting No. 2 Year 2022 has decided to set the policy for implementation and enforcement to exempt conformity assessment process by the Conformity Assessment Body (CAB) for registration of COVID-19 test kits with the Authority.**

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
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63000 Cyberjaya, Selangor, MALAYSIA
Tel: (+603) 8230 0300, Fax: (+603) 8230 0200
Emel: mdb@mda.gov.my

Thank you.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

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