






 Plot 112 International Finance Park, Gaborone
 Private Bag 2 Gaborone Station, Botswana
 info@bomra.co.bw

 (+267) 373 1720
 (+267) 373 1727
 (+267) 318 6254

Ref: MRA 1/8/5 VOL II (23)

03 August 2020

Attention: All Stakeholders

Dear Sir / Madam,

RE: Update-Medical Device Regulations

The above matter bears reference.

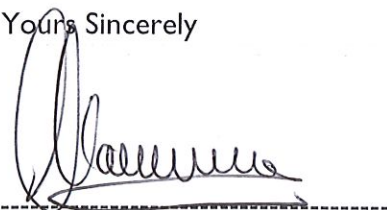
Botswana Medicine Regulatory Authority (BoMRA) is in the process of developing the legislative framework for the regulation of medical devices.

There are no applicable regulatory requirements to import or distribute medical devices apart from medical devices used in detection, prevention, and control of COVID-19. The import or distribution is not currently subject to any regulatory requirements pending approval of the relevant Regulations.

All the entities or individuals who sell, distribute, and import medical devices used in detection, prevention, and control of COVID-19 should apply for Exemption from Registration of Medical devices. Guideline and Form are available at www.bomra.co.bw.

Based on the current available science and information, antigen-detecting and antibody-detecting rapid diagnostic test kits for COVID-19 are not very specific and sensitive. They are therefore, still not recommended for the diagnosis of COVID-19. Following the recommendation from the World Health Organization for not recognizing any of these devices to date, BoMRA will not approve these for Covid-19 diagnosis.

Yours Sincerely



Dr Stephen Ghanie
Chief Executive Officer

Board Of Directors

Mr Duncan Thela (Chairperson) / Dr Mbalshi Mazwiduma / Dr Tiroyaone Mampame / Dr Gasellsewe Sento / Dr Gontle Moleele / Mr Kagiso Balopi
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