

PUBLIC NOTICE

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UPDATE ON LISTING OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS DEVICES

The Botswana Medicines Regulatory Authority (BoMRA) would like to inform relevant key stakeholders that the consolidation of listed Medical Devices and In-Vitro Diagnostics devices (IVDs) is currently ongoing.

Communication will be shared with Manufacturers and Authorized Representatives for the submitted medical devices and IVDs to provide missing documentation such as labels and declaration of conformities for the listed devices.

Stakeholders are notified that submitting a list of Medical Devices and IVDs to BoMRA does not guarantee that the listed devices are registered with BoMRA. Once the listing database is completed, stakeholders will be duly notified.

All COVID-19 related medical devices and IVDs should go through exemption process before they can be imported into the country.

The World Health Organisation list for Covid-19 related medical devices is shared in the below link in the medical devices guidelines section: <https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>

For any clarification regarding this exercise, please contact us at:
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