PUBLIC NOTICE

16TH September 2021

COVID-19 RELATED MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS DEVICES (IVDs) EXEMPTION REQUIREMENTS

The Botswana Medicines Regulatory Authority (BoMRA) would like to inform relevant stakeholders that; All COVID-19 related medical devices and IVDs should go through an exemption process before they can be imported into the country. A simplified schematic of the exemption process is shown in **Figure 1**. The WHO Priority medical devices list for the COVID-19 response and associated technical specifications is shared in the following link in the medical devices' guidelines: **https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2**.

The medical devices list includes but not limited to oxygen concentrators, pulse oximeters, medical Personal Protective Equipment (PPE), thermometers, invasive and noninvasive ventilators, Continuous Positive Airway Pressure equipment (CPAP), electrocardiograph and any other oxygen delivery devices and their consumables as listed in the WHO link above. The IVDs list includes but not limited to: Rapid antigen detection tests (**COVID 19 rapid antigen test kits approved by WHO only),** Nucleic Acid Detection Tests **(RT PCR test kits**), reagents and controls for COVID-19 analyzers.

Mandatory Requirements for Exemption:

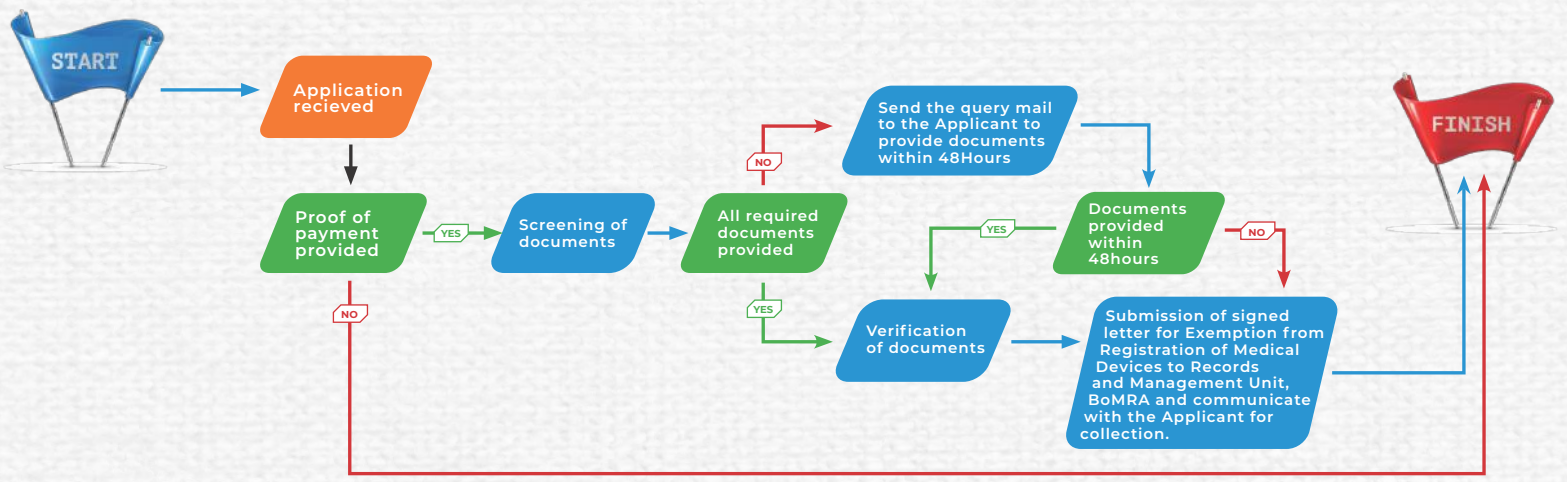
- Proof of payment BWP 350 per product and model (link: **https://www.bomra.co.bw/index.php/bomra-downloads/fees/category/50-bomra-banking details)**
- Copy of manufacturing license and/or ISO 13485 certificate or Business license or any proof of manufacturer's registration in the respective authorities.
- IFU/user manual of the medical device or IVD (Intended use should be in line with what is written in the IFU).
- A copy or proof of the Marketing Authorization and/or Free Sale Certificate issued by the relevant SRA or Singapore Health Sciences Authority or China National Medical Products Administration (Only for Class A & B medical devices & IVDs) or South African Health Products Regulatory Authority (Only for Class A & B medical devices) & IVDs and/ or CE certificate should be issued as per Medical Device Directives (93/42/EEC)/ In Vitro Device Medical Devices (Directive 98/79/EC)/ Regulation (EU) 2017/746 and show products approved) and/or In the case of WHO Prequalification-accepted products, a copy of a final acceptance letter. This shows the manufacturing site and the product code or model approved for Emergency Use Listing.
- Clear pictures of the sample to be imported along with manufacturer's instruction for use.
- Complete application form (link: **https://www.bomra.co.bw/index.php/bomra- downloads/forms/category/59-application-for-exemption**).
- For specific requirements per product, please refer to annexure I on the guidelines (link: **https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals/category/57-application- for-exemptions.**)

Kindly note.

- Exemption turnaround time (TAT) is 72 hours, and the exemption approval is valid for only 6 months.
- Recreational Oxygen in canisters and disinfectants are not medical devices and hence not regulated by BOMRA.
- Antibody detection test kits are currently still not allowed into Botswana.
- Clients are advised to ensure the medical device and IVD suitability to the intended use.

Your usual cooperation is highly appreciated. For any clarification regarding this exercise, please contact us at **medicaldevices.services@bomra.co.bw**

Figure 1: A simplified schematic of the exemption process



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