

## REGULATORY REQUIREMENTS FOR COVID-19 RAPID TEST KITS

### Communication to Stakeholders

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016, provides for the regulatory oversight of Medical Devices including In-Vitro Diagnostics (IVDs) in South Africa.

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2. COVID-19 Rapid Test Kits are classified as Class D Medical Devices according to Classification Rule 1 for IVDs - Detection of transmissible agents posing a high public health risk.  
*An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:*
  - a) *to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;*
  - b) *to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation.*
3. COVID-19 Rapid Test Kits may only be manufactured, imported, exported or wholesaled by medical device establishments that hold a valid Medical Device establishment licence issued by the South African Health Products Regulatory Authority (SAHPRA).
4. Regulation 21: Advertising of Medical Devices and IVDs states that only Class A and Class B Medical Devices and IVDs may be advertised to the public or a lay person.
5. COVID-19 Rapid Test Kits may not be advertised to the public or lay person.
6. COVID-19 Rapid Test Kits are intended for use by professionals only.
7. COVID-19 Rapid Test Kits are not intended for self-testing and may not be sold to the public or lay person.

8. Regulation 22.: Labelling of a Medical Device or IVD (p)(vi) requires that the labelling/packaging of the COVID-19 Rapid Test Kit contains an indication that the Medical Device or IVD is intended “for professional use only”.
9. Regulation 24: Instructions for use (IFU) of IVD (d) and (e) require that the instruction for use of the COVID-19 Rapid Test Kit contains an indication of the intended user and that it the IVD is for in vitro diagnostic use and for "professional use only”.
10. SAHPRA licensed Medical Device Establishments that are authorised to import COVID-19 Rapid Test Kits must submit:
  - a. Evidence of pre-market approval or registration for each listed COVID-19 Rapid Test Kit from at least one of the six jurisdictions recognised by SAHPRA (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualification by the World Health Organization (Refer to Guideline 16.03).
  - b. A Certificate of Free Sale confirming evidence that each listed COVID-19 Rapid Test Kit is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in at least one of the six jurisdictions recognised by SAHPRA.
  - c. Evidence of ISO13485:2016 certification of the original manufacturer for each listed COVID-19 Rapid Test Kit.
  - d. A copy of the Instructions for Use for each listed COVID-19 Rapid Test Kit.
  - e. A copy of labelling and packaging of each listed COVID-19 Rapid Test Kit
11. Any change in the product name or branding on the label/packaging/IFU will invalidate the originating approval of the COVID-19 Rapid Test Kit.
12. NOTE: These products may be referred to by similar names e.g. “COVID-19 POC (Point of Care) Test” or “Corona Self-test” and the same requirements are relevant and will be enforced, regardless of the name used.
13. Sale of such IVDs by a licence holder to an unauthorised person will be an infringement of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

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**CHIEF EXECUTIVE OFFICER OF SAHPRA**

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