SAHPRA
South African
Health Products
Regulatory Authority

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Ref. No. MDF V0058
Licence: 00001356MD_v1

V Care Medi Products Pty Ltd
373 Chief Albert Road
Pietermaritzburg
3200

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E-mail address parma.naik@gmail.com / parma.naik@vcaremed.co.za

ATTENTION: Mr PS Naik

Dear Sir/ Madam,

RE: AUTHORISATION FOR THE SALE OF COVID-19 Antigen POINT-OF-CARE TEST KIT – SARS-Cov-2 Ag test Rapid

Authorisation is hereby granted by the South African Health Products Regulatory Authority (SAHPRA), in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Medicines Act, to **V Care Medi Products Pty Ltd** , the holder of a licence to manufacture and/or distribute medical devices and in-vitro diagnostics (IVDs), issued in terms of Section 22C(1)(b) of the Medicines Act, to sell **StrongStep® SARS-CoV-2 Antigen Rapid Test** subject to the conditions provided below.

PRODUCT NAME	**StrongStep® SARS-CoV-2 Antigen Rapid Test**
ORIGINAL MANUFACTURER	**Nanjing Liming Bio-Products Co., Ltd.**
HOLDER OF LICENCE ISSUED ITO SECTION 22C(1)(B)	**V Care Medi Products Pty Ltd**
LICENCE NUMBER	**00001356MD_v1**
AUTHORISED REPRESENTATIVE	**Mr PS Naik**
SECTION 21 REFERENCE NUMBER	**MD21.202109/02**

Section 21 of the Medicines Act enables SAHPRA to authorise any person to sell during a specified period to any specified person or institution a specified quantity of any medical device or IVD which is not registered. Any medical device or IVD sold in pursuance of authority granted under Section 21 may be used for such purposes and in such manner and during such period as the SAHPRA may in writing determine.

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The sale of **StrongStep® SARS-CoV-2 Antigen Rapid Test** is subject to the **following conditions**:

1. Each test that is used for testing must be recorded and reported to the National Health Laboratory Service (NHLS) through the approved platform defined by the NHLS.

2. With regard to **post-market surveillance and adverse event reporting**:
   a) The licence holder is responsible for post-market surveillance and adverse event reporting in line with Regulation 17. Adverse event reporting and vigilance for medical devices or IVDs of the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016.
   b) Reports on product performance, use, post-market surveillance and adverse events must be submitted to SAHPRA on a monthly basis for all lots supplied to South Africa.

3. Requirements for **post-market surveillance and adverse event reporting**:
   a) The licence holder is responsible for post-marketing surveillance and adverse event reporting in line with *Regulation 17. Adverse event reporting and vigilance for medical devices or IVDs* of the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016.
   b) Prior to the sale of the COVID-19 Antigen test kit/s, the licence holder is required to submit to SAHPRA, and have approved, a post-market surveillance plan, in accordance with SAHPRA's post-marketing verification requirements.
   c) The licence holder is responsible for reporting as per the defined SAHPRA reporting protocol. Reports are to be submitted to SAHPRA on a monthly basis for all lots supplied to South Africa.

4. The licence holder should note that COVID-19 antigen test kits are for professional use only and should only be distributed to outlets where this condition can be adhered to**.**
   a) Results from antigen testing should be used for suspected Covid-19 cases and their close contacts to diagnose acute SARS-CoV-2 infection in areas where reference assay testing is unavailable, or turnaround times obviate its clinical utility.
   b) End-users, distributors and/or manufacturers must report any adverse event or product problem or suspected falsified product to SAHPRA.

5. Regulation 21(1) (a) of the Regulations Relating to Medical Devices and In vitro Diagnostics be followed, A Class C and Class D medical device/IVD may be advertised to Healthcare professionals only

SAHPRA may at any time by notice in writing withdraw any authority granted in terms of Section 21(1) if effect is not given to any determination made in terms of Section 21(2).

Please do not hesitate to contact me should you have any queries in this regard.

B Semete-Makokotlela

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER
Date: 24/09/2021