SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001431MD

LICENCE TO MANUFACTURE MEDICAL DEVICES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965
To act as a Manufacturer, Distributor, Importer and Exporter

This licence is granted to:

Licence Holder

South African Ventilator Emergency Project (SAVE-P)

Suite 33,Umhlanga Plaza
4 Lagoon Dr
Umhlanga Rocks
Durban
4320

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medical devices distributed, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22H, 23, 26, 28, 33 and the Regulations relating to Medical Devices 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant South African Health Products Regulatory Authority Guidelines.

This licence consists of 6 pages.

This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

DocuSigned by:
Boitumelo Semete-Makokotlela
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CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 26 June 2020

EXPIRY DATE: 26 June 2025

AMENDMENT DATE: N/A

This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

ANNEXURE 1 ***00001431MD***

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	YES	NO
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning or labelling)		
Single use		No
Measuring medical devices		No
Non-invasive medical device		No
Invasive medical devices		No
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other sterile medical devices (as specified):		No
Non-sterile Manufacture		
Measuring medical devices		No
Non-invasive medical devices	Yes	
Invasive medical devices		No
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other non-sterile medical devices (as specified):		No
Manufacture of *In Vitro* Devices (IVDs)		
Class A IVD		No
Class B IVD		No
Class C IVD		No
Class D IVD		No
End point Sterilisation of Medical Devices		No
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices		No
2. PACKAGING ACTIVITIES		
Packaging of bulk product and labelling		No
Re-labelling or redressing		No
Cartoning or secondary packaging	Yes	
Assembly or “kits” / procedure packs		No
3. TESTING ACTIVITIES		
Analytical		No
Microbiological		No
Sterility		No
Stability		No
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B		No
Distribution to hospitals and retail pharmacies and other clients: Class C	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class D		No

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	YES	NO
5. MATERIALS HANDLED OR STORED AT THIS SITE		
Combination medical devices with Penicillins		No
Combination medical devices with Cephalosporins		No
Combination medical devices with (other) Antibiotics (as specified):		No
Combination medical devices with Hormones		No
Combination medical devices with Cytostatics/Cytotoxics		No
Bulk Pesticides, Herbicides or Rodenticides		No
Radioactive material or Radioactive medical devices		No
Other potent, toxic, sensitising or hazardous materials (as specified):		No
6. IMPORT		
Import Class A medical device		No
Import Class B medical device		No
Import Class C medical device	Yes	
Import Class D medical device		No
Import Class A IVD		No
Import Class B IVD		No
Import Class C IVD		No
Import Class D IVD		No
Import RUO IVDs		No
7. EXPORT		
Export Class A medical device		No
Export Class B medical device		No
Export Class C medical device	Yes	
Export Class D medical device		No
Export Class A IVD		No
Export Class B IVD		No
Export Class C IVD		No
Export Class D IVD		No
Export RUO IVDs		No

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8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Authorised Representative	Manufacture / Import / Distribution / Export Control Person	Quality Control Person
Simone Rudolph-Shortt	Justin Corbett	Claudio Maccaferri
Dip Pharm Dip Production Mgt, LA ISO13485/ ISO9001 , SABS Textile Diploma	B.Comm HONS / MSc in Opaperations & Supply Chain Management	None

9. PARTICULARS OF THE LICENCE HOLDER CONTACT (Other than the Authorised Representative)

Name	Contact Details	Address
J Corbett	Tel: 031 561 1023 Cell: 082 443 9239 Fax: N/A Email: justin@randyork.com	Suite 33,Umhlanga Plaza 4 Lagoon Dr Umhlanga Rocks Durban 4320

10. LICENCE SPECIFIC CONDITIONS

1. The holder of the licence shall conduct all manufacturing, distribution or wholesaling operations in respect of those medical devices for which a registration certificate has been obtained, so as to ensure that the medical devices shall conform to the standards of quality, safety and performance applicable to them in accordance with the specifications made by the person to whose order they are manufactured, distributed or wholesaled or the specifications under which the medical devices are sold or supplied.

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11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

PRODUCT NAME	PRODUCT DESCRIPTION	ORIGINAL MANUFACTURER	STATUS
SAVE C-PAP 100	Ventilator	MCR Manufacturing Company (Pty) Ltd 117 Phillips Street, Rosslyn 0200, Gauteng, Republic of South Africa	Listing Authorised 26/06/2020 Section 21 Authorisation MD21:202006/05

1. The amendment to the Licence and the Section 21 Authorisation will be valid on condition that the raw usability data of the ventilator must be submitted within 30 days of receipt of the section 21 authorisation and the Section 22C(1)(b) licence.
2. Usability studies must be completed with first time users e.g. nursing sisters who do not have insight as to how the device works and would be able to operate the device in the correct manner on orientation.
3. The amendment to the Licence and the Section 21 Authorisation will be valid for up to twelve (12) months or until the cession of the circumstances justifying the authorisation of the emergency use of the ventilators during the Covid-19 pandemic, whichever may come first, and may be withdrawn or extended by the SAHPRA at any time.
4. The manufacturer and the device must comply with routine SAHPRA licence Section 22C(1)(b) licence requirements within 12 months from receipt of the licence and the Section 21 Authorisation.
5. SAHPRA must receive notification of any amendment to the device as soon as this is proposed. This is to give sufficient time for its consideration before being implemented.
6. The healthcare providers and hospitals are supplied with the necessary training, Instructions For Use and a description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown.
7. The patient to whom the device is administered is provided with a fact sheet/ Patient information leaflet that includes the following:

a. a description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
b. information regarding the individual's option to accept or refuse administration of the device; of the consequence, if any, of refusing administration of the device; and of the available alternatives to the device, including the benefits and risks of the available alternatives.

8. The labelling of the device(s) must state that; "This ventilator is not registered by the Authority and is only authorised for emergency use during the Covid-19 pandemic".
9. The ventilator must be affixed with a permanent label with the words 'Restricted non-invasive ventilator for emergency use during the Covid-19 pandemic, only to be used for emergency ventilation"

10. Where practical, all important instructions for the safe use of the device must be on the device. If this is not practical, they must always be in the same location as the device, even if this means tie wrapping it to the device or something similar.
11. Instructions for the cleaning, disinfecting, return or destruction must be provided
12. The device must demonstrate compliance with the essential principles for safety and performance; the device must be fit for the purpose intended and have been assessed as such.
13. The SAHPRA licence holder is responsible for ensuring that the necessary mechanisms are in place as indicated in the submission to SAHPRA, for monitoring the performance of the device supplied under these exceptional conditions.
14. Calibration of the device must be conducted at a known frequency as per manufacturers requirements in the User Manual and is the responsibility of the manufacturer
15. The SAHPRA licence holder is required to provide full details of all adverse incidents occurring in relation to the device or the use of the device
16. The SAHPRA licence holder is required to report to SAHPRA on the performance of the device every three months.
17. The SAHPRA licence holder is responsible for ensuring that the necessary mechanisms are in place to support the maintenance and/or servicing of the supplied device for the duration of use.
18. At the end of the derogation period the device supplied through this authorisation must be decommissioned or destroyed unless a further derogation is granted; the SAHPRA licence holder is required to provide evidence to SAHPRA confirming the decommissioning or destruction of the device supplied.
19. The use of general accessories (including disposables) for this device must be subject to appropriate scrutiny before being used with it.
20. Calibration of the device must be conducted at a known frequency as per manufacturers requirements in the User Manual and is the responsibility of the manufacturer.
21. The SAHPRA licence holder is responsible for ensuring that the necessary mechanisms are in place to support the maintenance and/or servicing of the supplied device for the duration of use.
22. At the end of the derogation period the device supplied through this authorisation must be decommissioned or destroyed unless a further derogation is granted; the SAHPRA licence holder is required to provide evidence to SAHPRA confirming the decommissioning or destruction of the device supplied.
23. The use of general accessories (including disposables) for this device must be subject to appropriate scrutiny before being used with it.