



FOOD, MEDICINE AND HEALTH CARE ADMINISTRATION AND
CONTROL AUTHORITY OF ETHIOPIA

Product Market Authorization Certificate

It is hereby certified that the Food, Medicine and Health Care Administration and Control Authority, being the authority responsible by law, for the control of Pharmaceutical and Medical Supplies in the country, has officially appraised, analyzed and granted registration certificate in Ethiopia for

Gradian Comprehensive Care Ventilator (CCV)

on the condition described in the schedule which forms part of this certificate

Signature of Authority

Product Market Authorization Certificate

Product Information

Product Name : Gradian Comprehensive Care Ventilator (CCV)

Generic name: Mechanical Ventilator

Device Category : 02 - Anesthetic and respiratory device

Device Class : Non - IVD - III

Device Group : Single

Indication : The ventilator is intended for use on one patient at a time, and only patients weighing greater than 5kg (11 lbs). This ventilator is intended to be used in the environments associated with emergency medical services (EMS), inter-hospital transport and hospital facility usage. The ventilator is intended to be used in temperatures of -17.7 to 50°C (0 to 122°F) and 5% - 95% relative humidity, non-condensing. The ventilator may be used for periods up to 30 days. The CCV can deliver breaths to the patient using an internal compressor as well as external gas sources.

General appearance : The Gradian Comprehensive Care Ventilator (CCV) is a portable emergency ventilator, which is designed to provide emergency respiratory support by means of a face mask or tube inserted into a patient's airway. The CCV is intended to be used as an electronically controlled gas powered emergency ventilator.

License holder : Gradian Health System, Inc.

Address : 915 Broadway, Suite 1001, New York, NY 1001, USA

Manufacturers

No	Company	Country	Address	Role
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1	Allied Healthcare Products, Inc.	United States (the)	1720 Sublette Avenue St. Louis, MO	Finished Product Manufacturer
2	Gradian Health Systems	United States (the)	40 W 25th St, 6th Floor New York, NY	Finished Product Release Controller

DEVICE ACCESSORIES

Raw materials

No	Name	Model	Description
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Standard accessory

No	Name	Model	Description
1	Bed hook & skid plate		Swivel hooks allowing for attachment of the ventilator to a bed, for use in transport
2	Power cord	Multiple	IEC cords to connect the ventilator and external battery to power (multiple: Type G, Schuko)
3	Humidifier one-pager		Laminated card as a quick reference for use and maintenance of the active humidifier
4	Humidifier breathing circuit		Reusable components for connection to the active humidifier (multiple: long tube, short tube, water trap, straight connector, elbow connector)
5	Stand base & wheels		Base and casters (2 locking) for ventilator stand
6	Reservoir hose		Standard hose for connection of the oxygen reservoir to a low pressure source
7	Reservoir hose hardware		Hardware recommended for more secure connection of the oxygen reservoir to low-pressure sources
8	Power strip		Multi-port power outlet for charging management of ventilator and accessories (multiple: Type G, Schuko)

9	Air hose		Standard hose to connect the ventilator to pressurized sources of medical air
10	Adult breathing circuit		Reusable single-limb breathing circuit
11	Basket		Additional stand basket for external battery and accessory storage
12	Exhalation valve		Reusable exhalation valve for use with single-limb circuits
13	Adult breathing circuit (disposable)		Single-use single-limb breathing circuit
14	Pulse oximeter	Multiple	Generic pulse oximeter with supporting accessories
15	Reservoir adapter		Fitting to allow connection of the oxygen reservoir to the ventilator
16	Pre-use Checklist		Laminated card as a quick reference for use and maintenance of the ventilator
17	User Guide		User guide containing information on the setup and operation of the device; available in English and French
18	Carrying handle		Sturdy handle attaching to the back of the ventilator, allowing for easy transport
19	Oxygen hose adapter	Multiple	Adapters to allow use of gas sources with different fitting standards; multiple adapters included (DISS to BS, AFNOR, NIST)
20	Power strip mounting hardware		Hardware necessary to mount accessories to the ventilator stand
21	Reservoir mounting band		Hardware necessary to mount the oxygen reservoir to the ventilator stand
22	Stand with handle & basket		Upright and accessories for ventilator stand
23	Adult HMEF	Multiple	Heat and moisture exchanging bacterial filter
24	Humidifier mounting hardware		Hardware necessary to mount humidifier to the ventilator stand
25	Peds HMEF	Multiple	Heat and moisture exchanging bacterial filter (low dead space)
26	Air hose adapter	Multiple	Adapters to allow use of gas sources with different fitting standards; multiple adapters included (DISS to BS, AFNOR, NIST)
27	Peds breathing circuit		Reusable single-limb breathing circuit (narrow bore)

28	External battery		External battery pack providing up to 14 hours of ventilator use; 12VDC, non-spillable lead acid
29	Humidifier	Multiple	Active humidifier heater
30	Air inlet particle filter (Bag of 3)		Replacement gross particle filters for the ventilator air compressor inlet
31	Test lung		Standard bag lung for use in machine function checks
32	Humidifier chamber		Reusable water chamber for active humidifier

Spare parts

No	Name	Model	Description
1	VSO solenoid		Replacement variable speed opening solenoid
2	Flow meter (oxygen)		Replacement mass flow sensor, calibrated for oxygen
3	Comprehensive maintenance kit		Kit containing internal and external components for planned and corrective maintenance procedures
4	Replacement label	Mulutiple	Replacement external vinyl labels
5	Replacement fitting	Multiple	Replacement internal and external fittings
6	Compressor		Replacement internal air compressor
7	External battery		External battery pack providing up to 14 hours of ventilator use; 12VDC, non-spillable lead acid
8	Internal battery		Extra internal back-up battery (up to 7hr, lead acid)
9	Flow meter (air)		Replacement mass flow sensor, calibrated for air
10	Air inlet particle filter (Bag of 3)		Replacement gross particle filters for the ventilator air compressor inlet
11	Display board		Replacement display circuit board
12	Flow board		Replacement flow circuit board

Detail Product Information

No	Model	Size	PackSize
1	AHP300	34 x 13 x 35 cm	1 PC ,

Further Information

Type of Registration :New Non - IVD
Shelf life (in months) :60
Registration No :02226/01947/NMDR/2021

Approval date :21-04-2022
Certificate validity time : 21-04-2027
Agent in Ethiopia :Caduceus

Note: This Certificate, unless previously suspended, revoked or varied as to the period of its validity, will continue in force until the validity date of the certificate.