MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

(Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya)

MEDICAL DEVICE REGISTRATION CERTIFICATE

This Registration Certificate is issued to

Gradian Health Systems Kenya Limited

for distribution and sale of

Gradian Comprehensive Care Ventilator

Registration Number:	**MD/2020/411**
Certificate Valid Until:	**11th February 2025**
Registration Date:	**12th February 2020**
Device Category:	**Class C**
GMDN:	
GMDN Term:	**Class C Active Medical Devices GMDN Code: 47769**

Intended Purpose:

The Gradian CCV is a comprehensive care ventilator that provides mechanical ventilation in a wide variety of settings—including those with unreliable access to oxygen and/or electricity

PPB LICENCE MD/2020/411 APPROVED

MAH Details:
GRADIAN HEALTH SYSTEMS LLC. SUITE 1001 10010 NEW YORK
Manufacturing Sites :
ALLIED HEALTHCARE PRODUCTS, ,

Device Accessories:

Device Group:

Device Sub-group/Sub-sets:

Conditions

The above Medical Device has been entered on the Record subject to the following conditions:

- The granted approvals herein are in accordance to the Laws of Kenya, Health Amendment Law 2019 and the applicant is required to adhere to the stipulated conditions.
- Each applicant/MAH/Product Owner shall retain records of the distribution of all of the applicant's medical devices included in the records for Medical Devices. In the case of records relating to a Class Active Implantable Medical Device (AIMD) medical device, Class C medical device, or Class B medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The applicant of a medical device shall keep an up to date log of information of all the medical devices registered.
- It is a condition of inclusion in the PPB that the applicant of a medical device that is an AIMD, Class for implantable Class B provides three consecutive annual reports to the Medical Devices Department , Directorate of Product Evaluation following registration of the Medical Device. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the PPB records must be for a period of at least six months but no longer than 18 months. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year.
- A applicant shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products Covered by This Entry

Product Specific Conditions

Pharmacy and Poisons Board
Head Office, Lenana Road
Po Box 27663-00506
Nairobi, Kenya

Serial NO: d58892501363fc735d3c12592162e3c2
Registration Date: 12-02-2020