MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

(*Health Act 2017*)

(*Health Amendment Rules of 2018*)

MEDICAL DEVICE CERTIFICATE

Issued to

Dedan Kimathi University of Technology Enterprises

for approval to supply

DeKUT Instant Hand Sanitizer

Registration Number:	**MD/2020/1085**
Certificate Valid Until:	**31st December 2020**
Device Category:	**Class A**
GMDN:	
GMDN Term:	

Intended Purpose:

Hand rub sanitizer solution with anti-viral and anti-bacterial activity

PPB LICENCE MD/2020/1085 APPROVED

MAH Details:
DEDAN KIMATHI UNIVERSITY OF TECHNOLOGY PRIVATE BAG-10143 10100 NYERI
Manufacturing Sites :
,

Device Accessories:

Device Group:
Sanitizer

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: **81f4dab58146e5703095caae110dd856**
Registration Date: **28-04-2020**