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

MARPE EGYMED LTD.

for distribution and sale of

Golden AR

Registration Number:	**MD/2023/1329**
Certificate Valid Until:	**06th September 2028**
Registration Date:	**07th September 2023**
Device Category:	**Class A**
GMDN:	
GMDN Term:	**61938**

Intended Purpose:

A collection of apparel items intended to be worn by healthcare staff during a patient examination or surgical procedure to maintain hygiene and prevent cross-contamination of microorganisms, body fluids, and particulate material between the patient and staff. It consists of one or more of the following types of items (which may be worn over a scrub suit): gowns, aprons, shoe covers, sleeve covers, caps, drapes, gloves and surgical face masks. It may in addition include items intended to be worn by the patient to prevent cross-contamination, and hand sanitizing products (e.g., alcohol gel). This is a single-use device

PPB LICENCE MD/2023/1329 APPROVED

MAH Details:
GOLDEN AR INDUSTRIES CORP.
Manufacturing Sites :
HTTP,

Device Accessories:

Â·Â Â Â Â Â Â Â Basic Gowns 1-Â Â Â Â Standard surgical gowns- Medium 2-Â Â Â Â Standard surgical gowns - Large 3-Â Â Â Â Standard surgical gowns â€“ X large 4-Â Â Â Â Standard surgical gowns â€“ XX large Â·Â Â Â Â Â Â Â Â Reinforced surgical gowns 1-Â Â Â Â Reinforced surgical gowns â€“ medium 2-Â Â Â Â Reinforced surgical gowns - Large 3-Â Â Â Â Reinforced surgical gowns â€“ X large 4-Â Â Â Â Reinforced surgical gowns -XX large Â·Â Â Â Â Â Â Â Â Protective gowns 1-Â Â Â Â Protective gowns â€“long sleeve knitted cuff 2-Â Â Â Â Protective gowns- long sleeve elastic cuff 3-Â Â Â Â Protective gowns â€“ half sleeve Â·Â Â Â Â Â Â Â Â Hair cover 1-Â Â Â Â Hair cover with tie (surgeon Cap) 2-Â Â Â Â Elastic Hair cover (Nurse Cap) Â·Â Â Â Â Â Â Â Â Face mask 1-Â Â Â Â Face mask with ear loop 2-Â Â Â Â Face mask with tie Â·Â Â Â Â Â Â Â Â Shoe cover 1-Â Â Â Â Show cover PP, , , , , , , , , , , , , , , ,

Device Group:

Device Sub-group/Sub-sets:

Basic Gowns 1- Standard surgical gowns- Medium 2- Standard surgical gowns - Large 3- Standard surgical gowns ? X large 4- Standard surgical gowns ? XX large Reinforced surgical gowns 1- Reinforced surgical gowns ? medium 2- Reinforced surgical gowns - Large 3- Reinforced surgical gowns ? X large 4- Reinforced surgical gowns -XX large Protective gowns 1- Protective gowns ?long sleeve knitted cuff 2- Protective gowns- long sleeve elastic cuff 3- Protective gowns ? half sleeve Hair cover 1- Hair cover with tie (surgeon Cap) 2- Elastic Hair cover (Nurse Cap) Face mask 1- Face mask with ear loop 2- Face mask with tie Shoe cover 1- Show cover PP

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: **5b148ae10a17b3c726fa4a39378cd357**
Registration Date: **07-09-2023**