FDA-2019GV4DGXOPFJ3S21MLY1JO

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

Registration Status : INITIAL
FDA Registration No. :MDR-08778
Classification :

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs. Device and Cosmetics Act, the product described hereunder has been found to conform with the requirements and standards for registration of medical devices per existing regulations in force as of date hereof.

Name of Product : SURGICAL GLOVES (STERILE, POWDER-FREE)
Size/Code: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

Manufacturer : Beta Healthcare Products Pvt. Ltd. - Kerala, India

Trader :

Importer : Hexagon Medical Supplies - 1335 G. Araneta Avenue, Barangay Sto. Domingo, Quezon City

Distributor : Hexagon Medical Supplies - 1335 G. Araneta Avenue, Barangay Sto. Domingo, Quezon City

Approved Use : Intended use to protect patient and user from cross-contamination and for use in invasive surgery.

Claimed Shelf-Life : 5 years

This registration shall be valid for one year(s) and shall expire on 15 October 2020 subject to the conditions listed on the reverse side.

No change in the information, labelling and commercial presentation of this product shall be made during the effectivity of this registration without approval of this Office.

This registration is subject to suspension, cancellation or recall should violation of any provisions of R.A. 3720, as amended, and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this 15th day of October, 2019.

BY AUTHORITY OF THE DIRECTOR GENERAL

ENGR. BAYANI C. SAN JUAN, MSc, MNSA, CESE
Director IV

DTN :20190207135106
O.R. No :1075387
Amount :P 1,515.00
Date Issued :7 February 2019
/MLSB

FDA-0450178

MANDATORY REQUIREMENT:

1. This product must be available only in drugstores, hospitals and other legal outlets.
2. The labelling of each device must state:
   a) The date (month/year) within which to use said device, whenever applicable.
   b) The lot or batch number, whenever applicable.
   c) Product registration number.
   d) Name and address of local distributor/importer.

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right privilege to the use of the name or brand so registered; Registrant hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or industrial design rights arising from the registration of the product(s) listed on the other side hereof.