FDA-2018Y7UI37EZOJ3GXUBY7O2L

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

Food and Drug Administration PHILIPPINES

Registration Status : INITIAL
FDA Registration No. : MDR-06597
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 : SILVERSTREAM® CHRONIC WOUND MANAGEMENT
Sizes: PET Bottles of 500ml, 250ml, 100ml

Manufacturer : EnzySurge Ltd. - Rosh Ha'ayin, Israel

Trader :

Importer : First Associated Medical Distribution Co., Inc. - Blk 18 Lot 14, Philip St., Multinational Village, Moonwalk, Sucat, Parañaque City

Distributor : First Associated Medical Distribution Co., Inc. - Blk 18 Lot 14, Philip St., Multinational Village, Moonwalk, Sucat, Parañaque City

Approved Use : Intended to be used for management and moisturizing of wound such as stage I, IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds.

Claimed Shelf-Life : 3 years

This registration shall be valid for one year(s) and shall expire on 13 March 2019 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 13th day of March, 2018.

BY AUTHORITY OF THE DIRECTOR GENERAL

Bayani San Juan

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

DTN :20171109084650
O.R. No :0895235
Amount :P 1,515.00
Date Issued :9 November 2017
/MGAD

DUPLICATE

FDA-0256920

File Property of FAMED Co., Inc.

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.