

Registration Status
FDA Registration No. : DVR-XXXX
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 : BRAND XXX

Manufacturer : YYY Private Limited - Singapore

Trader

Importer :

Distributor :

Approved Use :

Claimed Shelf-Life

This registration shall be valid until 20 December 2018 subject to the conditions listed on the reverse side.

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

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

Witness My Hand and Seal of this Office, this 14th day of July, 2014.

BY AUTHORITY OF THE SECRETARY OF HEALTH

RSN: BHD-T-R-2013-XXXX / BHD-T-R-2014-XXXX

O.R. No : 048XXXX / 056XXXX

Amount :

Date Issued : 15 November 2013 / 27 June 2014

SIGNATURE

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.

<Description on all available product types>

SIGNATURE

Date Amended: 26 November 2014. This Certificate of Product Registration (CPR) is amended to change the importer/distributor to **COMPANY Z – LOCATION OF COMPANY.**

SIGNATURE/DATE

SAMPLE