



-Official Emblem-

CERTIFICATE OF REGISTRATION FOR MANUFACTURING OF MEDICAL DEVICES

Certificate no. Sor Phor.7/2553

THIS CERTIFICATE OF REGISTRATION IS GIVEN TO

SURETEX LIMITED

Represented by: Miss Niramol Bunnuan has been registered as manufacturing location of name Suretex Limited

Locate at: 31/1, Suratthani – Thakuapha Road, Moo 4, Tambon Khao Hua Kwai, Amphur Phunphin Suratthani 84130, Thailand, Post Code 84130 telephone 077 277 400

Place of Storage of Medical Device 1 : 31/1, Suratthani – Thakuapha Road, Moo 4, Tambon Khao Hua Kwai, Amphur Phunphin Suratthani 84130, Thailand, Post Code 84130, telephone 077 277 400

Place of Storage of Medical Device 2 : N/A

For Manufacturing Medical Device: Urology

Person whose control of manufacturing process under section 6(7) N/A

This certificate valid up to date 31st December 2557 B.E. (A.D 2014) and is valid only at the place mentioned in this certificate only

Given on date 9th August 2553 B.E.

Mr. Pongphan Wongmanee

DEPUTY SECRETARY GENERAL
FOR SECRETARY-GENERAL OF FOOD AND DRUG ADMINISTRATION

(OFFICIAL SEAL)

Certified correct translation: Kanwadee Jamjang

To Renew Certificate of Registration of location for Manufacturing of Medical Device

Renewal no. 1

This Certificate renewal is valid until
date 31st December 2562 B.E onward.

Miss Yuwadee Patanawong
Senior Expert of Medical Device Safety
Acting Director of Medical Device Control Division
For Secretary-General of
Food and Drug Administration

(OFFICIAL SEAL)

Renewal no. 2

This Certificate renewal is valid until
date 31st December

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Renewal no. 3

This Certificate renewal is valid until
date 31st December

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Renewal no. 4

This Certificate renewal is valid until
date 31st December

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THAI FDA. A4 0630877


Certified correct translation: Kanwadee Jamjang

Detail of Amendment no. 1/2557

Allowed to change place of manufacturing as same location

1. Add manufacturing of medical device (plant3) for Polyisoprene Synthetic latex condom
2. Add area of packing
3. Add area of Storage of Medical Device

Effective from 10 November 2557 B.E. onward

Miss Yuwadee Patanawong
Senior Expert of Medical Device Safety
Acting Director of Medical Device Control Division
For Secretary-General of
Food and Drug Administration

(OFFICIAL SEAL)

Added Detail Amendment

Scope of medical device as Certificate of registration for Manufacturing of Medical Device is Urology (Condom)

Effective from 19 December 2557 B.E. onward

Miss Yuwadee Patanawong
Senior Expert of Medical Device Safety
Acting Director of Medical Device Control Division
For Secretary-General of
Food and Drug Administration

(OFFICIAL SEAL)

Detail of Amendment no. 1/2560

Allowed to add registered items to establishments.

1. Add the scope of medical equipment produced in one group Surgery (Lubricating Gel UMDN Code 12401)
2. Change the layout of the production and storage area of storage of Medical Device in the original place

Effective from 21 July 2560 B.E. onward

Miss Yuwadee Patanawong
Director of Medical Device Control Division
For Secretary-General of
Food and Drug Administration

(OFFICIAL SEAL)


Certified correct translation: Kanwadee Jamjang

Detail of Amendment no. 1/2561



Allowed to change Represented person from Miss Niramol Bunnuan to Mr. Somchai La-ard

Effective from 18 April 2561 B.E. onward

Mrs. Korrapat Trisarnsri
Pharmacist Senior Professional Level
Acting Director of Medical Device Control Division
For Secretary-General of
Food and Drug Administration

(OFFICIAL SEAL)

Certified correct translation: Kanwadee Jamjang