Thailand

Legal

Legal framework: Yes


Notes: 1. Medical Device to be licensed
   1.1 Condom
   1.2 Examination glove
   1.3 Surgical glove
   1.4 Disposable hypodermic hygienic syringe
   1.5 Disposable insulin syringe
   1.6 HIV test for diagnosis, screening
   2 Medical Device To Be Notified
   2.1 HIV Test for other purposes
   2.2 Medical equipment for physical therapy
   2.3 Alcohol-detector test equipment
   2.4 Silicon breast implant

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Food and Drug Administration, Medical Device Control Division - http://www.fda.moph.go.th/eng/medical/index.stm

Responsibilities of the NRA: Medical Device Control Division, Thai - Food and Drug Administration, is an organization which regulates and monitors Quality, Standard, Efficiency and Safety of medical devices manufactured, imported and sold in Thailand abide by Medical Device Act B.E. 2551 (A.D. 2008), Ministerial Regulation and Notice of The Ministry of Public Health.

Medical device definition

Medical device defined: Yes

Text: Medical device means
(1) Equipment, products or articles used in the medical profession; the profession of nursing and midwifery, of the clinical practice of medicine or of veterinary as prescribed by the legislation concerned;
(2) Equipment, products or articles that have effects on the health, the structure or any functions of the human or animal body;
(3) Constituents, components, accessories or parts of the equipment, products or articles under (1) or (2);
(4) Other equipment, products or articles prescribed by the Minister as medical device by publication in the Government Gazette. “Produce” means make, assemble or devise; repackage separately or collectively; as well as recycle by transmuting, modifying or sterilizing. Medical Device Act, § 3.

In vitro diagnostic medical device (IVD) defined: N/A

Text: N/A

Medical device classification

Classification: N/A

Categories: N/A

Classification rules: N/A

Classification rules details: N/A

Essential principles

Essential principles: Yes

Details: Registrant of establishment who wishes to produce or import medical device under Section 6 (8) shall submit an application to the licensor for the assessment that such medical device has efficiency, quality, standard and safety for use including assessment of its effect and feasibility in economic and social aspects to implement the use of the medical device in appropriateness widely and fairly and after the licensor has issued the assessment certificate it may produce or import.

Medical Device Act, B.E. 2551 (2008), Section 22

Conformity assessment

Conformity assessment bodies: Yes

Details: Medical Device Act, B.E. 2551 (2008), Chapter 8: Competent Official, Sections 61-66

This section describes the powers and duties of the competent official.

Pre-marketing / procedure: Yes Seven categories of medical devices require premarket approval: (1) condoms, (2) examination gloves, (3) surgical gloves, (4) sterile hypodermic disposable syringes, (5) sterile insulin disposable syringes, (6) HIV test kits for diagnostic use, and (7) contact lenses. Manufacturers and importers of HIV test kits must have a quality control accreditation. Licensed Medical Devices.

Four categories of devices require an application for notification to the Thai FDA prior to manufacture or importation. Notification Medical Devices.
Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: “Any person who wishes to produce or import medical device must register its establishment to the licensor.” Medical Device Act, B.E. 2551 (2008), Section 15
Listing of medical devices: Yes
Details: Any person who wishes to distribute medical device under Section 6(3) shall submit an application for the permission and after the licensor has issued the license it may distribute such medical device. Medical Device Act, B.E. 2551 (2008), Section 24

Import controls
Import controls: Yes
Details: It is prohibited to import (or produce) a medical device unless a license has been granted by the licensor. Medical Device Act, § 12. A person who has permission to import (or produce) may also distribute the medical device imported (or produced) by him or herself. Id. § 13.

Post market controls
Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: The registrant of establishment, licensee or notifier shall perform as follow:
(1) Control and supervise the operation of produce, import or distribute of medical device to comply with quality standard of production, importation or distribution of medical device under Section 6(5) Medical Device Act, B.E. 2551 (2008), Section 41 (1)

Enforcement: Yes
Details: Penalties (ranging from monetary fines to imprisonment) vary depending on the type of violation under the Medical Device Act. See §§ 57-82.
Competent officials may inspect medical devices. If the device is found to be below standards, rendering the device unsafe or harmful to health, the licensor (authority) may be issue written orders to improve or alter the device or to cease production, importation, or distribution of the device. The licensor may also publicize the results of the inspection. Medical Device Act, § 19.
A competent official may enter the premises of production, importation, distribution or storage of the medical device to inspect. It may also take samples and confiscate related information in case of reasonable suspicion of violations of the act. Medical Device Act, § 44.

Adverse event reporting: Yes
Details: The licensee (importer, distributor, or producer) must submit reports on adverse reactions of the medical device to the Secretary General of the Food and Drug Administration. Medical Device Act, § 30.

Field safety corrective action monitoring: Yes
Details: “...if a medical device is with quality or standard or efficiency not consisting with the permission or details notified, not safe for use that may be hazardous to health or change in standard, the General Secretary shall:
(2)issue a written order .. to alter or improve the medical device; (3) ..to suspend the production, importation or distribution; (4)announce the inspection result or analysis of medical device and announcement on violation or non-compliance with (2) or (3) to the public”
Medical Device Act, B.E. 2551 (2008), Section 41

Advertising: Yes
Details: It is prohibited to falsely advertise a medical device. The licensor must grant approval of any advertisement with a commercial purpose for a medical device. Medical Devices Act, § 42.

Labelling: Yes
Details: A medical device for sale must have labelling information in Thai (in font that is at least as large as information in another language) on:
- name, category and type of medical device
- name and premises of the producer or importer
- content
- lot numbers
- license number
- instructions for use and storage
- warnings and precautions
- expiry date
- other information
Medical Devices Act, § 33.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.