(Draft)

Announcement of the Food and Drug Administration on Notification of Possession, Movement, Inspection of Readiness, and Costs of Medical Devices that Require Technology Assessment under Section 6 (8) of the Medical Devices Act B.E. 2551 B.E. ...

As per the statements in section 21, paragraph 3 of the Medical Devices Act B.E. 2551, the secretary of the Food and Drug Administration has announced the following.

1) This announcement will be effective after 180 days of the government gazette announcement.
2) This announcement does not apply to the medical devices in the announcement of the ministry of public health on the medical devices that require technology assessment B.E. 2563 on 27 April 2020.
3) After the announcement of the medical device requiring technology assessment as per section 6 (8), the manufacturers, the importers, the sellers or the possessors, who are in the possession of the mentioned medical devices, must notify the TFDA with a notification letter indicating the possession of the medical devices with the following details:
   3.1) Name of the medical devices
   3.2) Quantity of the medical devices
   3.3) Numbers or letters that indicate the manufacturing batches or serial numbers
   3.4) Certificate numbers of licensed, notified or listed medical devices (if applicable)
   3.5) Name and address of the possessor
   3.6) A map that shows the location of the medical devices and any places nearby
   3.7) A diagram that shows where the medical devices are stored or used.

4) In case of the movement of the medical devices from one place to another after notifying the possession, the possessor must inform the TFDA at least 7 days before the movement except in exceptional circumstances. Also, the possessor must inform about the readiness of the medical devices, location and related personnel.

Once notified, the medical devices could be transferred from one place to another, except for the case that the inspection has to take place to ensure the safety of the medical device.

5) The medical device possessor shall be responsible for any expense of the readiness inspection.
6) In terms of notifying and contacting about this regard, the notifier can proceed online as per Electronic Performance Act.

In the case that it cannot be done as an electronic document, the notifier shall proceed as normal or at the TFDA or at any authority as specified in the TFDA announcement.

Announcement Date……..