Announcement from Medical device division

1. The license holder need to prepare the documents that indicate the quality, efficacy and safety of the medical device. The documents can be in the form of
    a. Documents or electronic documents
    b. In Thai or English
    c. Can be kept at the manufacturer site or the importer site
2. In case the license holder would like to discontinue to market the medical device, the following process should be done
    a. For the medical device with no expiry date, the documents needed to be kept not less than 5 years from the manufacturing date
    b. For the medical device with expiry date, the documents needed to be kept not less than 1 year from the expiry date
3. In case the staff is visiting the site, please show the documents directly to the staff. However, if the staff is asking for the documents, please submit the documents in time.
4. The list of the documents that indicate the quality, efficacy and safety of the medical device are

List of the documents	Type of the medical device			
	1	2	3	4
1. Status of the registration ex. Imported license	●	●	●	●
2. General name and trade name of the medical device	●	●	●	●
3. Code of the medical device	●	●	●	●
4. Name and address of the manufacturer	●	●	●	●
5. Name and address of the company/person responsible for marketing the product	●	●	●	●
6. Executive summary	●	●	●	●
7. Essential Principles of Safety and Performance of Medical Device and method used to demonstrate conformity				●
8. Device Description 8.1. Device description and features 8.2. Purpose of use 8.3. Indication 8.4. Instruction of use 8.5. Storage 8.6. Shelf life 8.7. Contraindication/Warning/Precautions 8.8. Adverse events 8.9. Other Alternatives therapy 8.10. Components of the medical device	●	●	●	●

8.11. Product specification				
9. Summary of design verification and validation documents				●
10. (Test report) Batch report/ Lot release	●	●	●	●
11. Device Labeling	●	●	●	●
12. User manual	●	●	●	●
13. Risk analysis				●
14. Manufacturer information				●
15. ISO certificate	●	●	●	●
16. Letter of authorization for authorized representatives (For the importer)	●	●	●	●
17. Method of wasted disposal and destruction after use	●	●	●	●
18. Report of adverse events	●	●	●	●

5. The regulations become effective from 13 June 2020 for class 1,2 and 3 Medical device and from 11 September 2020 for class 4 Medical device.
6. If any license holder didn't comply with the regulations, the license holder are subject to up to one year imprisonment or a fine up to 100,000 or both.