Thailand

Latest Updates

Software	
Embedded Software	Classification following to main instruments Class is dependent on the instrument class, which follows the highest risk classification on the reagents used.
Software as Medical Device (SaMD)	According to Medical Device Act B.E. 2551 (2008), Section 4 (1) stated the meaning of medical device also included the software that required to be registered "Medical device" means: (1) an instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for one or more of the specific purpose(s) of: .....
Clinical Decision Support Software (CDS)	No updates at present.
Change Management Requirements for Software/SaMD	No updates at present.
Quality Management System (QMS)	Class 2-4 devices all require ISO 13485 certificates to certify the quality system/s of the legal and/or actual manufacturing facilities.
Post-Market Management	No updates at present.

Real World Data/Evidence
No updates at present.

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	No updates at present.
Deep Learning	No updates at present.

Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity

No updates at present.

Data Privacy

No updates at present.

Labelling

UDI	No updates at present.
Specific Market Requirements	No updates at present.