



UPDATES FROM ASEAN MEDICAL DEVICE COMMITTEE (AMDC)

25th AHWP/GHWP Online Annual Meeting

31 November & 1 December 2021

ONE VISION, ONE IDENTITY, ONE COMMUNITY

ABOUT ASEAN MEDICAL DEVICE COMMITTEE (AMDC)

ASEAN Medical Device Directive (AMDD)



- Harmonised Regulatory Regimes among ASEAN Member States
- signed on 21 November 2014

ASEAN Medical Device Committee (AMDC)

- Committee formed to oversee the implementation of the Directive

AMDD Agreement: <http://agreement.asean.org/media/download/20141204115621.pdf>

RATIFICATION OF AMDD

2015	2016	2018	2019	2020	2021	Yet to ratify
 Laos	 Vietnam	 Indonesia	 Cambodia	 Malaysia	 Philippines	 Brunei Darussalam
 Singapore		 Myanmar			 Thailand	

AMDD Ratification Status: <http://agreement.asean.org/agreement/detail/307.html>

CURRENT WORK OF AMDC

- Transposition of AMDD to the national regulation
 - Development of **guiding principles** for implementation of AMDD:
 - i. Common Submission Dossier Template (CSDT),
 - ii. Post Market Surveillance (PMS),
 - iii. Registration and Licensing, and
 - iv. Interpretative notes for Implementation of AMDD.
- Formalization of a **post-marketing system**
- Harmonised **Risk Classification** for Medical Devices and make harmonised decision on **Borderline Products**
- Adoption of harmonised Medical Devices **Standards** which was earlier identified by ACCSQ-WG1.
- Following the activities of, and participating in AHWP/GHWP and IMDRF.



10th ASEAN Medical Device Committee Meeting





10th ASEAN Medical Device Committee Meeting



THANK YOU!



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