ASEAN MEDICAL DEVICE DIRECTIVES [AMDD] UPDATES

The ASEAN Medical Device Committee (AMDC) was formed in 2014 (earlier was ACCSQ-MDPWG) to coordinate the implementation of the AMDD, an agreement between the 10 ASEAN members states to harmonise medical device regulatory framework. The key objective is to facilitate trade and market access of medical devices in ASEAN by reducing technical barriers.

- Establishing common understanding of AMDD through the development of an interpretive matrix.
- Harmonising requirements for adverse events reporting through the implementation of guidelines on post market surveillance.
- Aligning the risk classification of medical devices across ASEAN member states.

UPDATE ON AMDD RATIFICATION STATUS

Year of Ratification	2015	2016	2018	2019	2020 (projected)
	 Laos	 Vietnam	 Myanmar	 Cambodia	 Malaysia (Apr 2020)
Pre-market Post-market	2020 2013		2015 2020	2012 2019	2012 2020
	 Singapore		 Indonesia		 Brunei Darussalam
Pre-market Post-market	2012 2007		2010 2010		2022 2022
					 Thailand
Pre-market Post-market					2012 2016
					 Philippines
Pre-market Post-market					1992 2020