



KEY POINTS FOR MEMBER STATES UPDATE IN REFERENCE TO PROVISIONS IN AMDD

9TH AMDC, 6TH-7TH AUGUST 2020



**Medical Device Control Division
Thai Food and Drug Administration**



Legislation

	Act	Risk Classification	Establishment License	Pre Marketing	Labeling	Post Marketing	Product Over claim	GCP
Singapore	✓	✓	✓	✓	✓	✓	✓	✓
Indonesia	✓	✓	✓	✓	✓	✓	✓	✓
Malaysia	✓	✓	✓	✓	✓	✓	✓	✓
Thailand	✓	✓	✓	✓	✓	✓	✓	▲
Philippines	✓	✓	✓	✓	✓	▲	✓	▲
Cambodia	✓	▲	✓	✓	▲	✓	✓	▲
Lao PDR	▲	▲	✓	▲	▲	▲	✓	▲
Myanmar	▲	▲	✓	▲	▲	▲	▲	✓
Brunei	▲	▲	▲	▲	▲	▲	▲	▲
Vietnam								

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Establishment License

	Manufacturer	Importer	Distributor
Singapore	✓	✓	✓
Indonesia	✓	✓	✓
Malaysia	✓	✓	✓
Philippines	✓	✓	✓
Lao PDR	✓	✓	✓
Thailand	✓	✓	▲
Cambodia	▲	✓	✓
Myanmar	✓	▲	▲
Brunei	▲	▲	▲
Vietnam			

2.2 Establishment License

- Manufacturer
- Importer
- Distributor
- Wholesaler
- Retailer
- All Distributor

Post marketing

	Adverse Event	FSCA	Distribution Records	Complaint Records
Singapore	✓	✓	✓	✓
Indonesia	✓	✓	✓	✓
Malaysia	✓	✓	✓	✓
Thailand	✓	✓	✓	✓
Philippines	▲	▲	▲	▲
Cambodia	✓	▲	▲	▲
Lao PDR	▲	▲	▲	▲
Myanmar	▲	▲	▲	▲
Brunei	▲	▲	▲	▲
Vietnam				

2.5 Post market controls

- Report of adverse event (AE) and medical device malfunction
- Report of FSCA
- Importation and distribution records
- Complaint records