

Building the ASEAN Community

Medical Device

Reducing Technical Barriers while Safeguarding Public Health



Medical device sector is one of the priority sectors for integration in ASEAN. To support the freer flow of these products in the region, ASEAN Member States (AMS) have agreed to reduce the differences on national standards, technical regulations and conformity assessment procedures in medical device sector.

To date 13 medical device standards have been identified as 1st priority for harmonization and alignment with international standards. A Common Submission Dossier Template (CSDT) has been developed and implemented to assist both regulator

and business operator in managing product. Guidelines on Risk Classification of General Medical Device and Guideline on Risk Classification of IVD Medical Device have also been developed and implemented.

To help improve patient safety standards across the region as well as providing a more straightforward path to market in the region for manufacturers of medical devices, the ASEAN Medical Device Directive (AMDD) was developed and signed by the ASEAN Economic Minister in 2014. The AMDD provides a harmonized system of placement of medical devices into ASEAN market, based on common key requirements / components of medical device regulatory controls.

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