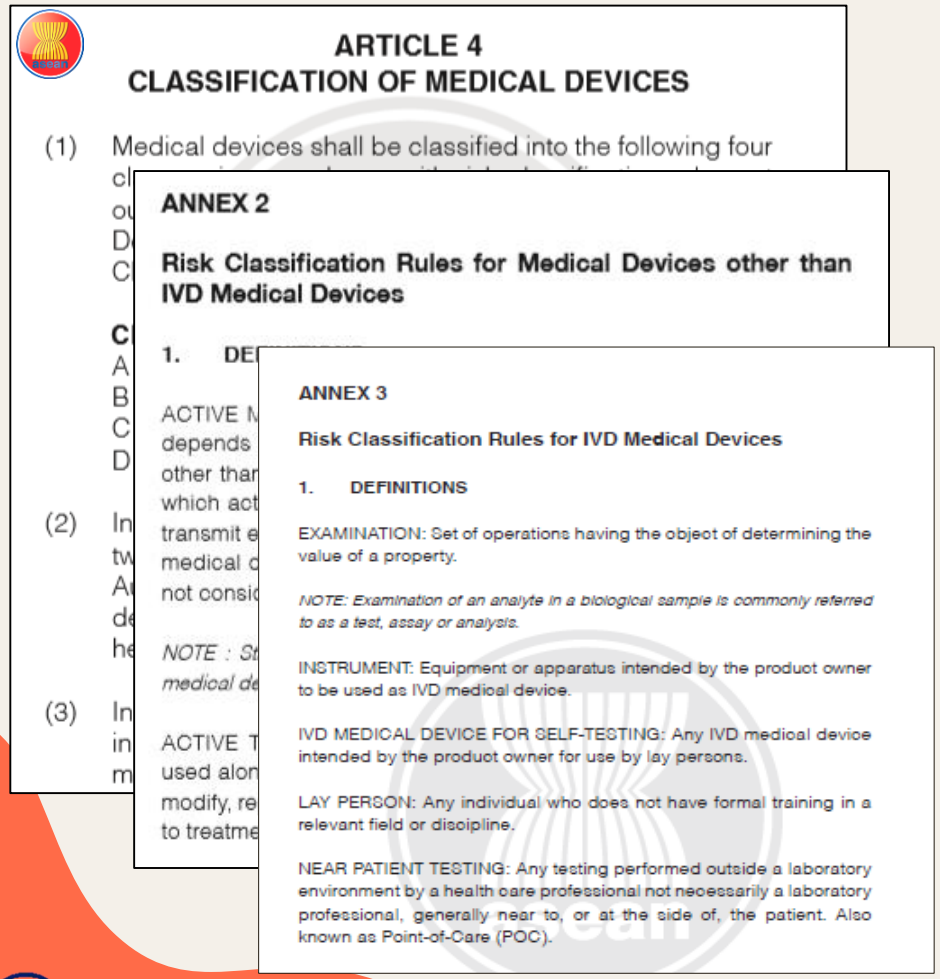
Medical Device Regulation in 2021

The new regulations are aligned with ASEAN Medical Device Directive (AMDD)



ARTICLE 4
CLASSIFICATION OF MEDICAL DEVICES

(1) Medical devices shall be classified into the following four

ANNEX 2

Risk Classification Rules for Medical Devices other than IVD Medical Devices

ANNEX 3

Risk Classification Rules for IVD Medical Devices

1. DEFINITIONS

EXAMINATION: Set of operations having the object of determining the value of a property.

NOTE: Examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

INSTRUMENT: Equipment or apparatus intended by the product owner to be used as IVD medical device.

IVD MEDICAL DEVICE FOR SELF-TESTING: Any IVD medical device intended by the product owner for use by lay persons.

LAY PERSON: Any individual who does not have formal training in a relevant field or discipline.

NEAR PATIENT TESTING: Any testing performed outside a laboratory environment by a health care professional not necessarily a laboratory professional, generally near to, or at the side of, the patient. Also known as Point-of-Care (POC).