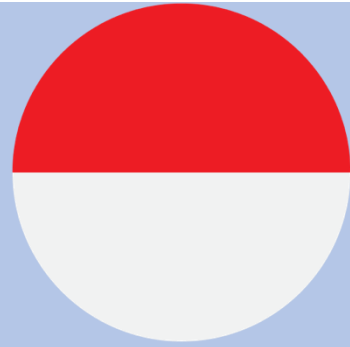


Indonesia



Latest Updates

Software	
Embedded Software	It is registered as part of the main instrument. Will be classified as per medical device risk classification
Software as Medical Device (SaMD)	Should be registered as stand-alone medical device. Classified as Risk B Product Category. Registration Requirements follow the general registration requirements with addition of ISO 62304.
Clinical Decision Support Software (CDS)	No updates at present.
Change Management Requirements for Software/SaMD	No updates at present.
Quality Management System (QMS)	Follow ISO 13485 standard.
Post-Market Management	No updates at present.

Real World Data/Evidence

No updates at present.

Artificial Intelligence (SiMD & SaMD)

Machine Learning	No updates at present.
Deep Learning	No updates at present.
Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity

No updates at present.

Data Privacy

No updates at present.

Labelling

UDI	No updates at present.
Specific Market Requirements	No updates at present.