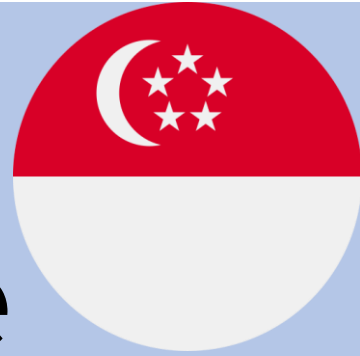


Singapore



Latest Updates

Software	
Embedded Software	<p>HSA has issued a guidance on Regulatory Guidelines for Software Medical Devices – A Lifecycle Approach. This guidance covered both embedded software and standalone software (SaMD, AI etc). The document mainly referred to existing guidances on GMD and IVD with some focus on software specific requirements, eg. cybersecurity and AI. No qualification and risk classification were mentioned.</p> <p>https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach_r2-(2022-apr)-pub.pdf?sfvrsn=851e8c13_2</p>
Software as Medical Device (SaMD)	<p>29 April 2022: HSA published its revised Regulatory Guidelines for Software Medical Devices (https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach_r2-(2022-apr)-pub.pdf)</p>
Clinical Decision Support Software (CDS)	<p>On April 2022, the HSA released "Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS) https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/guidelines-risk-classification-samd-cdss-(2022-apr)-pub68164581f0d548c29794b7c61b3c8dfc.pdf</p> <ul style="list-style-type: none">• If the intended use meets the definition of a medical device in the First Schedule of Health Products Act (HPA), then it would be subject to regulatory controls by HSA and considered a SaMD• CDSS intended for medical purposes such as investigation, detection, diagnosis, prevention, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process; will be classified as a medical device subject to regulatory controls by HSA <p>The CDSS will not be regulated as a medical device if: the intended use does not meet the definition of a medical device in the First Schedule of Health Products Act (HPA)</p> <p>OR</p>

	<p>the CDSS is intended solely for the display or printing of medical information* about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies or recommendations)</p> <p>*Does not include real time patient information intended for patient monitoring or treatment decisions</p>
Change Management Requirements for Software/SaMD	<p>Link: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-21-r5-guidance-on-change-notification-for-registered-md-(2023-mar)-pub.pdf?sfvrsn=fd98324_2</p>
Quality Management System (QMS)	<p>Link: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-33-r2-guidance-on-the-application-of-singapore-standard-gdpmds-(2023-sep)-pub.pdf?sfvrsn=d6a33416_2</p>
Post-Market Management	<p>Companies involved in distributing SaMD in Singapore (manufacturers, importers, wholesalers and registrants) are required to comply with their post-market duties and obligations which includes reporting of device defects or malfunctions, recalls, Field Safety Corrective Actions and serious injuries or death associated with use of the device.</p> <p>Ref: https://www.hsa.gov.sg/docs/default-source/announcements/regulatory-updates/regulatory-guidelines-for-software-medical-devices--a-lifecycle-approach.pdf</p> <p>Ref: Refer to "Safety Monitoring" at https://www.hsa.gov.sg/medical-devices/guidance-documents</p>

Real World Data/Evidence	
No updates at present.	

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	<p>Guideline Published Oct 2021: AIHGle https://www.moh.gov.sg/docs/librariesprovider5/equides/1-0-artificial-in-healthcare-guidelines-(aihgle)_publishedoct21.pdf</p>
Deep Learning	No updates at present.
Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity	
<p>Healthcare Security Essentials published by MOH , supported by CSA, August 2021: https://www.moh.gov.sg/docs/librariesprovider5/hrq-cybersecurity/healthcare-cybersecurity-essentials.pdf</p>	
<p>Artificial Intelligence in Healthcare Guidelines (AIHGle), October 2021: https://www.moh.gov.sg/docs/librariesprovider5/equides/1-0-artificial-in-healthcare-guidelines-</p>	

[\(aihgle\)_publishedoct21.pdf](#)

Ref: <https://www.csa.gov.sg/our-programmes/certification-and-labelling-schemes/cls-md>

Data Privacy

Digital Mental Health - Ethical Data Collection Standards - None found in SG by Antoinette (Safe Space).

Do we follow Australia's National Safety and Quality Digital Mental Health (NSQDMH) Standard to draft regulation framework and certification?

<https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards>

Advisory Guidelines for Healthcare Sector [pdpc.gov.sg]

Labelling

UDI	Refer to "UDI" at https://www.hsa.gov.sg/medical-devices/guidance-documents
Specific Market Requirements	Cybersecurity Labelling Scheme for Medical Devices (CLS MD). Still voluntary.