

27 Feb 2026



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Singapore: HSA updates guidelines on risk classification of SaMD and qualification of CDSS

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30 Jul 2025 □ 2 minute read

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In brief

On 21 July 2025, the Health Sciences Authority (HSA) revised its guidelines on the risk classification of software as a medical device (SaMD) and the qualification of clinical decision support software (CDSS).

The revised guidelines incorporate changes to improve online searchability and international alignment on terminology, provide better clarity on the classification of SaMDs under Class B and include additional criterion to determine whether or not a CDSS is considered a medical device.

In more detail

The following are the notable changes to the guidelines:

- **Refinements to terminology:** The title of the guidelines has been changed to “Guidelines on Risk Classification of SaMD and Qualification of Clinical Decision Support Software (CDSS)” to improve online searchability. For better international alignment, the term “Standalone Medical Mobile Applications” has been revised to “SaMD.”
- **Class B medical device criterion for SaMDs:** HSA has clarified that SaMDs will be classified as Class B if they are intended to analyze, measure or monitor (i) a vital physiological process (e.g., heart rate, blood pressure, respiratory rate, body temperature) or (ii) anatomical structure images (e.g., X-rays of bones, ultrasound images of organs, intraoral images) in order to drive clinical/patient management. This clarification is in line with HSA’s guidance on the risk classification of general medical devices.

- **Clarification on CDSS qualification:** HSA has provided clarification on when CDSS would not be regulated as a medical device, i.e., where the output and recommendations of CDSS are solely based on established clinical guidelines. HSA has also provided further examples of nonmedical device CDSS.

Key takeaways

HSA's continuous updates to its guidelines in relation to SaMDs, especially to bring better alignment with international standards, illustrate that HSA is closely monitoring digital health related developments and will ensure that its guidelines evolve in tandem with advancements in the medical technology space.

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