

Software as Medical Device (SaMD)

SaMD refers to **medical purpose software** that **operates independently without hardware**

Definition

Standalone software, not part of a medical device, used for medical purposes

IMDRF Framework

Internationally harmonized SaMD classification and regulatory system

Risk Classification (IMDRF Framework)

Level I

Informational purpose

Level II

Diagnostic support

Level III

Treatment decision

SaMD Examples

- Image analysis software (lesion detection, measurement)
- Clinical Decision Support Systems (CDSS)
- Remote patient monitoring apps
- AI-based diagnostic algorithms



Key Point: SaMD is distinguished from general wellness apps and is regulated as a medical device when used for diagnosis, prevention, monitoring, treatment, or mitigation of disease