Guidelines on Risk Classification of Standalone Medical Mobile Applications (SaMD) and Qualification of Clinical Decision Support Software (CDSS)

Medical Devices Cluster

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INTRODUCTION
Objective

- This guideline takes reference from the IMDRF's Framework for Software as a Medical Device (SaMD)[1] to determine the risk classification of Standalone Mobile Applications that are Medical Devices (commonly referred as SaMD).

- This guideline also provides clarity on the qualification of Clinical Decision Support Software (CDSS) as regulated medical devices or otherwise, as well as the current regulatory approach and requirements for such software that are regulated by HSA.

- The guidelines reflect HSA's current policy stance and practice, and should not be misconstrued as new regulatory controls on software medical devices and CDSS.

[1] IMDRF, Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations, 18 September 2014

INTRODUCTION
Definitions

Standalone Mobile Application *(as defined in the Health Products (Medical Devices) Regulations)*

A software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

NOTE: These are commonly referred to as Software as Medical Devices (SaMD)

CLASSIFICATION
Risk Classification Framework

The Risk Classification Framework for Standalone Mobile Applications (i.e. SaMD) will take into consideration the following:

i. The **significance of information provided by the standalone mobile application** to healthcare decision: to treat or diagnose, to drive clinical management, or to inform clinical management and;

ii. The **state of the patient's healthcare situation or condition**: critical, serious, or non-serious

iii. Existing **GN-13 Guidance on Risk Classification** of General Medical Devices and the risk classification rules therein

IMDRF, Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations, 18 September 2014

Treat or to diagnose

Treating and diagnosing infers that the information provided by the Standalone Mobile Application will be used to take an immediate or near term action:

- To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human body
- To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition).

CLASSIFICATION
Risk Classification Framework

Drive clinical/patient management

Driving clinical/patient management infers that the information provided by the Standalone Mobile Application will be used to aid in treatment, aid in diagnosis, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions:

- To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
- To aid in treatment as an adjunct to standard clinical treatment
- To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis.
- To triage or identify early signs of a disease or conditions.

Inform clinical/patient management

Informing clinical/patient management infers that the information provided by the Standalone Mobile Application will be used:

- To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
- To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)

Critical situation or condition

Situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health. The Standalone Mobile Application is considered to be used in a critical situation or condition where:

- The type of disease or condition is:
  - Life-threatening state of health, including incurable states,
  - Requires major therapeutic interventions,
  - Sometimes time critical, depending on the progression of the disease or condition that could affect the user's ability to reflect on the output information.
- Intended target population is fragile with respect to the disease or condition (e.g., pediatrics, high risk population, etc.)
- Intended for specialized trained users.

Serious situation or condition

Situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health. The Standalone Mobile Application is considered to be used in a serious situation or condition when:

- The type of disease or condition is:
  - Moderate in progression, often curable,
  - Does not require major therapeutic interventions,
  - Intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations.
- Intended target population is NOT fragile with respect to the disease or condition.
- Intended for either specialized trained users or lay users.

Non-Serious situation or condition

Situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health. The Standalone Mobile Application is considered to be used in a non-serious situation or condition when:

The type of disease or condition is:

- Slow with predictable progression of disease state (may include minor chronic illnesses or states),
  - May not be curable; can be managed effectively,
  - Requires only minor therapeutic interventions, and
  - Interventions are normally noninvasive in nature, providing the user the ability to detect erroneous recommendations.
- Intended target population is individuals who may not always be patients.
- Intended for use by either specialized trained users or lay users.

Non-IVD Standalone Mobile Applications (SaMD)

Risk Classification Table

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical / patient management	Inform clinical / patient management
Critical	C	C	B
Serious	C	B	A
Non-serious	B	A*	A

* Standalone Mobile Applications will be classified as Class B if intended to image, measure or monitor a physiological process to drive in clinical/patient management

To determine the risk classification of IVD Standalone Mobile Application please refer to GN-14 Guidance on the Risk Classification of IVD Medical Devices

CLASSIFICATION
Examples

Software intended for healthcare professionals to acquire and monitor physiological signals from devices to detect early signs of mild sleep apnoea

Significance of information	To drive clinical management; software provides information to predict and identify the early signs of mild sleep apnoea
State of Healthcare situation or condition	Non-serious condition; mild sleep apnoea can be managed effectively and requires only minor therapeutic interventions
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B*	

* SaMD will be classified as Class B if intended to image, measure or monitor a physiological process to drive in clinical/patient management

CLASSIFICATION
Examples

Software intended for lay users to analyse self taken photographs of moles to identify unusual or irregular moles that could indicate an increased risk of melanoma

Significance of information	To drive clinical management; the software provides information to the lay user to assist in the identification of atypical moles that could be a risk factor for melanoma
State of Healthcare situation or condition	Serious condition; intended target population is not fragile with respect to the disease or condition; intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

CLASSIFICATION
Examples

Software intended for healthcare professionals to analyse electrocardiogram data to aid in the diagnosis of heart arrhythmias

Significance of information	To drive clinical management; provides information to clinicians to aid in the diagnosis of arrhythmia
State of Healthcare situation or condition	Serious condition; do not require major therapeutic interventions. Additionally, the intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health.
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

CLASSIFICATION
Examples

Software intended for healthcare professionals to provide cognitive behaviour therapy as an adjunct to contingency management system, for patients with substance use disorder

Significance of information	To drive clinical management; intended to aid in treatment of patients with substance use disorder, used as an adjunct to standard clinical treatment.
State of Healthcare situation or condition	Serious condition; do not require major therapeutic interventions. Additionally, the intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health.
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

CLASSIFICATION
Examples

Software intended for healthcare professionals to analyse a patient's skin lesion images to aid in the classification of malignant and benign lesions

Significance of information	To drive clinical management; the software provides information to the clinician to assist in the evaluation of potentially malignant lesions
State of Healthcare situation or condition	Serious condition; do not require major therapeutic interventions. Additionally, the intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health.
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

CLASSIFICATION
Examples

Software intended for healthcare professionals to collect and analyse vital sign readings to triage or risk stratify patients for risk of Major Adverse Cardiac Event (MACE) at the emergency department

Significance of information	To drive clinical management; software is used to triage, risk stratify or identify early signs of a disease or conditions
State of Healthcare situation or condition	Critical condition; timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class C	

CLINICAL DECISION SUPPORT SOFTWARE
Background

- Clinical Decision Support Software (CDSS) are standalone software (including mobile applications, cloud based and web-based software) that can perform a wide range of functions for healthcare professionals, patients and caregivers to support clinical practice, clinical and patient management.

- Not all CDSS in the market are medical devices, this document serves to provide clarity in qualification of CDSS i.e. in identifying a CDSS that may be classified as a medical device and on the risk classification of CDSS medical devices based on the risk classification table presented in page 11 of this document.

CLINICAL DECISION SUPPORT SOFTWARE

Intended Use

- The intended use of the CDSS, taking into account the way the product is designed and/or presented will determine whether it will be regulated as a medical device.

- 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.

- 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.

CLINICAL DECISION SUPPORT SOFTWARE
Qualification

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).

OR

the CDSS 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)

*Does not include real time patient information or data

CLINICAL DECISION SUPPORT SOFTWARE
Qualification

CDSS that are medical devices will be classified as Class A medical devices if they meet **all** of the below criteria:

1) Intended to analyse medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies or recommendations)

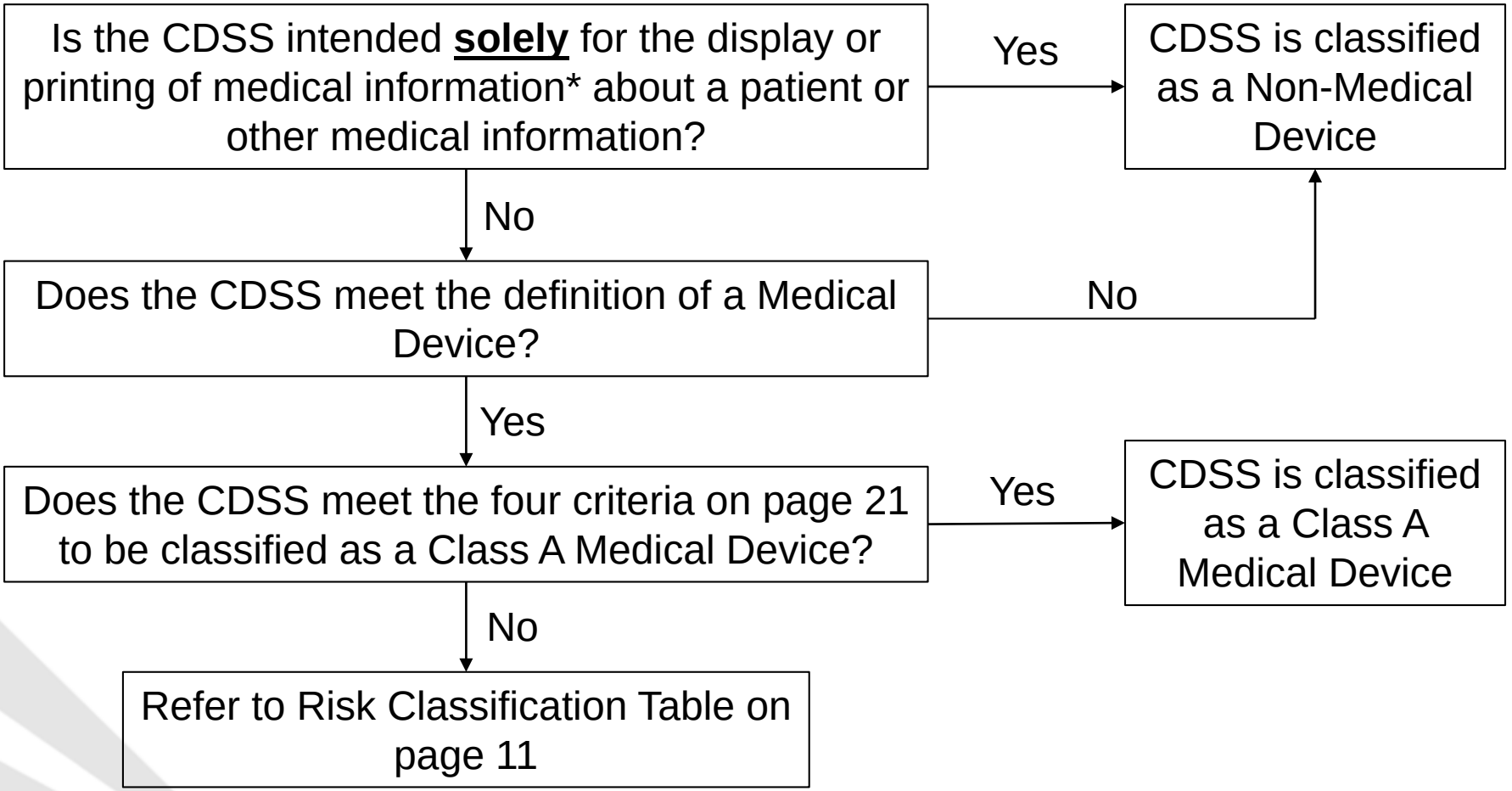
2) Not intended to acquire, process, or analyse a medical image, signal or pattern from another medical device, IVD or signal acquisition system

3) Intended only to support healthcare professionals in making decisions about prevention, diagnosis, treatment or alleviation of a disease or condition

4) Not intended to replace the clinical judgement of a healthcare professional to make a clinical diagnosis or treatment decision regarding an individual patient and the healthcare professional is able to independently review the basis for the recommendation.

CLINICAL DECISION SUPPORT SOFTWARE

Qualification



*Does not include real time patient information or data

CLINICAL DECISION SUPPORT SOFTWARE

Non-MD CDSS

Software that are solely intended for the display and printing of medical information or do not meet the definition of a medical device are not regulated as medical devices.

Such software typically do not analyse any patient specific information and do not provide any recommendations to the prevention, diagnosis, treatment or alleviation of any disease or condition.

CLINICAL DECISION SUPPORT SOFTWARE

Non-MD CDSS Examples

- Patient appointment and surgery schedule management software
- Software intended for patient billing purposes
- Calculator software for clinicians to perform simple medical calculations (Eg: BMI, Water content, Convert from mmol/L to mg/dL)
- Laboratory Information Management System (LIMS) or Laboratory Information System (LIS) to support a laboratory work flow and data tracking
- Software incorporating a digitised clinical decision flow with no analysis performed on patient information
- Software that displays information (Eg: Dosage) about drugs or medical devices that are consistent with approved labels
- Software for tracking of the end user's diet or exercise for diabetes management without connection to a blood glucose meter

CLINICAL DECISION SUPPORT SOFTWARE

Non-MD CDSS Examples

- Software performing a diary function (Eg: Daily recording of pain scores, bowel function)
- Electronic Health Record software intended to display, receive, collect and store patient medical records and data with no processing or analysis
- Software intended for providing medical information (Eg: Clinical guidelines) to healthcare professionals for reference, quality assurance or training purposes
- Software solely intended to allow healthcare professionals to perform teleconsultation or telecollaboration and communicate between clinicians or patients
- Survey or chat-based triaging software intended to indicate to users on appropriate steps to take based on user indicated symptoms
- Software solely to promote general wellness of users

CLINICAL DECISION SUPPORT SOFTWARE

Non-MD CDSS Examples

- Software that provides calendar tools for tracking of menstrual cycles
- Software that provides calendar tools to for tracking of progress through IVF treatment cycles
- Drug dosage calculator based on established clinical calculation methods
- Software performing a library function to allow users to match patient specific information to reference information based on established clinical guidelines or literature (Eg: Criteria for diagnosis of diabetes based on plasma glucose readings)

CLINICAL DECISION SUPPORT SOFTWARE
Class A CDSS

Software that meet all four criteria on page 21 may be classified as a Class A medical device.

Such software typically perform the analysis on patient test results and symptoms and do not perform any analysis on images. They do not directly control the performance of therapeutic devices and the healthcare professional is able to independently verify the recommendation through available clinical guidelines.

CLINICAL DECISION SUPPORT SOFTWARE

Class A CDSS Examples

Software intended for healthcare professionals to analyse a patient's symptoms and test results against accepted clinical guidelines to recommend specific diagnostic tests or therapy

Criteria	Met?
Intended to analyse medical information about a patient or other medical information	Yes; software analyses the patient's symptoms and test results
Not intended to acquire, process, or analyse a medical image, signal or pattern	Yes
Intended only to support decision making about prevention, diagnosis, treatment or alleviation of a disease or condition	Yes
Not intended to replace the clinical judgement of a healthcare professional	Yes; recommendations provided by the software is based on clinical guidelines

CLINICAL DECISION SUPPORT SOFTWARE

Class A CDSS Examples

Software intended for healthcare professionals to analyse a patient's test results to recommend the most appropriate surgical action and describes a surgical workflow based on accepted clinical guidelines

Criteria	Met?
Intended to analyse medical information about a patient or other medical information	Yes; software analyses the patient's test results
Not intended to acquire, process, or analyse a medical image, signal or pattern	Yes
Intended only to support decision making about prevention, diagnosis, treatment or alleviation of a disease or condition	Yes
Not intended to replace the clinical judgement of a healthcare professional	Yes; recommendations provided by the software is based on clinical guidelines

CLINICAL DECISION SUPPORT SOFTWARE

Class A CDSS Examples

Software intended for healthcare professionals to analyse a patient's DNA sequence to provide treatment recommendations for cancer based on accepted clinical guidelines

Criteria	Met?
Intended to analyse medical information about a patient or other medical information	Yes; software analyses the patient's DNA sequence data
Not intended to acquire, process, or analyse a medical image, signal or pattern	Yes
Intended only to support decision making about prevention, diagnosis, treatment or alleviation of a disease or condition	Yes
Not intended to replace the clinical judgement of a healthcare professional	Yes; recommendations provided by the software is based on clinical guidelines

CLINICAL DECISION SUPPORT SOFTWARE

Class A CDSS Examples

Software intended for healthcare professionals to aid in the interpretation of variants in the genomic profiling of liquid biopsy samples based on published literature

Criteria	Met?
Intended to analyse medical information about a patient or other medical information	Yes; software analyses the patient's DNA sequence data
Not intended to acquire, process, or analyse a medical image, signal or pattern	Yes
Intended only to support decision making about prevention, diagnosis, treatment or alleviation of a disease or condition	Yes
Not intended to replace the clinical judgement of a healthcare professional	Yes; recommendations provided by the software is based on published literature

CLINICAL DECISION SUPPORT SOFTWARE

Other CDSS

Software that do not meet any of the four criteria on page 21 will be classified based on the Non-IVD SaMD Risk Classification Table on page 11.

Such software may include software that analyses images or directly influence or control the performance of therapeutic devices or when the healthcare professional is unable to independently verify the recommendation made by the software driven by its built-in algorithms or artificial intelligence.

CLINICAL DECISION SUPPORT SOFTWARE

Other CDSS Examples

Software intended for healthcare professionals to acquire and analyse raw DNA sequencing data to provide a list of drugs to avoid for patients with G6PD enzyme deficiencies based on established guidelines

Is the four criteria met?	No; software acquires and analyses a signal from an IVD
Significance of information	To inform clinical management; information is based on existing clinical guidelines and software serves to provide clinical information by aggregating relevant information
State of Healthcare situation or condition	Non-serious condition; G6PD deficiency is a non-serious condition which can be managed effectively
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class A	

CLINICAL DECISION SUPPORT SOFTWARE

Other CDSS Examples

Software intended for healthcare professionals to analyse a patient's images to annotate anatomical features that could indicate fetal or toddler's growth or development delays based on accepted clinical guidelines

Is the four criteria met?	No; software analyses a medical image
Significance of information	To inform clinical management; information is based on existing clinical guidelines and software serves to provide clinical information by aggregating relevant information (Eg toddler's height, weight, head circumference)
State of Healthcare situation or condition	Serious condition; delay in growth may be due to underlying medical conditions (e.g. growth hormone deficiency, hypothyroidism), this may require timely interventions to mitigate any long term irreversible consequences on individual patients
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class A	

CLINICAL DECISION SUPPORT SOFTWARE

Other CDSS Examples

Software intended for healthcare professionals to analyse a patient's images to annotate anatomical features for therapy or surgical removal

Is the four criteria met?	No; software analyses a medical image, healthcare professional is unable to independently review basis for recommendation
Significance of information	To drive clinical management; the annotation of anatomical features to aid in the treatment of the patient
State of Healthcare situation or condition	Serious condition; accurate annotation of anatomical features is critical to ensure that the treatment is carried successfully to mitigate long term irreversible consequences on an individual
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

CLINICAL DECISION SUPPORT SOFTWARE

Other CDSS Examples

Software intended for healthcare professionals to analyse genotyping data to provide personalised drug combinations and dosage recommendations for management of transplant patients

Is the four criteria met?	No; healthcare professional is unable to independently review basis for recommendation
Significance of information	To drive clinical management; information provided by software is used to aid in management of liver transplant patients
State of Healthcare situation or condition	Serious condition; accurate recommendation of drug combination and dosage is critical to avoid unnecessary interventions. Additionally, intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health
Risk Classification of SaMD as per Non-IVD SaMD Risk Classification Table: Class B	

REFERENCES

IMDRF, Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations, 18 September 2014

Health Canada, Software as a Medical Device (SaMD): Definition and Classification, 03 October 2019

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