Health Canada Santé Canada

Draft Examples Document

Software as a Medical Device (SaMD)

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Ébauche du document d'exemples

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

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1. Non-IVDD SaMD

1.1 Examples of Class I SaMD

- Software that is intended for use in rehabilitation (i.e. upper extremity, cervical region, etc.) and active range of motion (ROM) assessment. This software analyzes images from cameras to generate objective measurements of joint mobility and posture. The data generated by the software is intended to function as a clinical aid in the assessment and rehabilitation of joint dysfunction and posture imbalance.
- A mobile software app that receives alerts from hospital event management software to indicate that a patient monitor is sounding an alarm. Similar to beeper functionality, the alert just informs the HCP that a patient monitor has rendered an event (alarm etc.). The alert does not provide any specific physiological data, measurements or medical images.

1.2 Examples of Class II SaMD

- Software that acquires patient data, such as blood pressure, heart rate, weight, etc., from connected medical devices and transmits it to a healthcare professional (HCP) for remote patient monitoring. This includes software that can provide real-time feedback based on symptoms and generate alerts for the clinician if patient vitals are outside of an established range.
- Software that manipulates or analyzes images and other data obtained from a radiological device (e.g., CT, bone density, and distance) to create 3D models of the region intended to be used in planning orthopedic/dental surgical treatments with a device.
- Software that customizes the patient-specific surgical plan and instrumentation based on analysis of imaging and device characteristics for orthopedic or dental implant procedures.
- Software intended for health care professionals that uses an algorithm undisclosed to the user to analyze patient information, such as blood pressure, heart rate, weight, age, etc., to determine which treatment plan is likely to be most effective in treating the patient's condition.
- Desktop-based software running on a PC that analyzes previously recorded physiological signals from adult patients to stage sleep, detect arousals, and measure snoring to allow a physician to assess sleep quality to identify patients with obstructive sleep apnea.
- Software that leverages the use of a smartphone otoscope attachment and the smartphone camera to perform an ear exam by capturing a video of the inside of a child's ear in order to receive a clinical diagnosis. The software serves as the interface that launches the camera, captures the image, performs storage and sharing functions, and may or may not have analytical functionality.
- Software that is designed to aid radiologists in the detection of pulmonary nodules during review of CT examinations of the chest. This solution is intended for annual lung cancer screening for at risk patients where the early detection of nodules can significantly prolong survival rates.

- Software that calculates percent breast density from the same digital mammograms that radiologists view in breast screening exams to aid radiologists in the assessment of breast tissue composition. Breast density is an important part of the mammography process as dense breasts have a higher risk of developing breast cancer and the dense breast tissue makes it challenging to differentiate it from cancer on an x-ray image. The software is intended for the evaluation of individual breast cancer risk and to make decisions about any additional screening modalities that might be beneficial for further assessments.
- Mobile app intended for people with tinnitus and a compatible hearing aid. The app is intended to be used as a sound therapy tool in a tinnitus treatment program that is prescribed by a licensed hearing healthcare professional (audiologist, hearing care specialists, and otolaryngologists) who is trained in tinnitus management.
- Breast imaging software intended for use with a digital mammography system. The software displays images from multiple modalities, which include X-ray mammography images, breast ultrasound and MRI. The software allows selection, display, manipulation, quantification (i.e. measurements such as area and distance within a region of interest), markup, print composition and media exchange of breast images. The software is intended to analyze digital mammography images and identify regions of interest, such as microcalcification clusters and density masses, which may warrant further review by a radiologist. The software is intended for softcopy reading and interpretation of digital mammography images by Radiologists.

1.3 Examples of Class III SaMD

- Software that performs diagnostic image analysis for making treatment decisions in patients with acute stroke, i.e., where fast and accurate differentiation between ischemic and hemorrhagic stroke is crucial to choose early initialization of brain-saving intravenous thrombolytic therapy or interventional revascularization.

2. IVDD SaMD

2.1 Examples of Class II IVDD SaMD

- A software app that reads urinalysis test strips that can be used for screening urinary tract infections. The user takes a picture of the dipstick from a smartphone camera which is then processed by an image processing algorithm to detect pads on the dipstick and their true colors. The app reads the urine dipstick and automatically detects pad colors for diagnosis of 10 indicators. The user can monitor and track the progress of each indicator over time.

2.2 Examples of Class III IVDD SaMD

- A prenatal screening software application intended for use in clinical laboratories to analyze diagnostic assays to aid in estimating the risk of having a fetus with congenital abnormalities such as Down's Syndrome (Trisomy 21), Edward's Syndrome (Trisomy 18), Patau's syndrome (Trisomy 13) and open Spina Bifida (OSB). Users include qualified laboratory technicians and senior laboratory personnel.

- Qualitative software intended for high resolution identification of HLA alleles by means of sequencing-based typing (SBT) using data generated by Next Generation Sequencing (NGS), to inform clinical management. This software is intended to be used for transplantation purposes and in silico diagnostic use by professional health care personnel, such as laboratory technicians and physicians, trained in HLA-typing and DNA sequencing in diagnostic laboratories.

3. Software that is not subject to the Regulations

It is Health Canada's current position that the software examples below do not meet the definition of a device as outlined in the Food and Drugs Act and therefore, are not subject to the Regulations.

- Software that provides patients with simple tools to organize and track their health information. These are apps that provide patients with tools to organize and track health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include: apps that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan.
- Electronic Health Record (EHR) - An application software program, and/or algorithms used as or in an information system to electronically receive, collect, store, manage, display, output, and distribute data, within or between healthcare facilities, to support the electronic registration and documentation of patient clinical data. It typically enables healthcare providers to review and update patient medical records, place orders (e.g., for medications, procedures, tests), and sometimes view multimedia data from many specialties.
- Software that meet the definition of Medical Device Data Systems (MDDS). These are apps that are intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device. These mobile apps include those that are used as a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring (i.e., mobile apps that meet the MDDS definition).
- Chat-based triage software intended to provide triage advice to guide users to the most appropriate form of help based on their medical symptoms. The chat-based triage software outcomes are intended to indicate to a user the next best step to take when seeking further health care, and to provide safe and appropriate clinician-vetted advice where appropriate. Triage advice outcomes include self-care, pharmacy, primary care, dental, ophthalmic, sexual health and emergent care advice outcomes.
- Standalone software intended to be used as an annotation tool for the production of diagnostic and prognostic reports of clinical EEG studies, based on a user's traditional visual interpretation of EEG in an external EEG display application. It is intended to standardize

and structure reporting of clinical EEG according to an international academic standard. The software is intended to reduce the workload of the reporting doctor by automatically importing minimal pieces of information from an external EEG system.

- Software that incorporates a risk calculator based on well-established third party risk models available in the public domain to generate a score for obese individuals at risk of developing heart disease. This includes software applications intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools and routinely used in clinical practice. This software is tailored for clinical use, but retains functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators.
- Software that provides supplemental care by coaching or educating patients to help them manage their health in their daily environment. This includes software that complements professional clinical care by facilitating behavioral change or coaching patients with specific diseases or identifiable health conditions in their daily environment. Examples include software that coaches patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promotes strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting.
- Software that provides patients with simple tools to organize and track health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include: software that provides simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan.
- Software that serves as a medical image storage device by providing electronic storage and retrieval functions for medical devices or software that serves as a medical image communication device by providing electronic transfer of medical image data between medical devices.