Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Guidance Document on Qualification of Medical device Software

Authoring Group: Work Group 3, Pre-market: Software as a MD

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1. Objectives

This document was developed by Work Group 3 of GHWP Technical Committee to provide guidance and information to Regulatory Authorities (RAs) and the Medical Device Industry (Industry) on the Software Qualification and Classification.

The main aim of developing this document for medical device software qualification is to provide information to GHWP members economies' RAs and industry in establishing, a consistent approach to determine the qualification of a software based on its intended use and determine its classification as a medical device or otherwise. Appropriate classification of the medical device software is the key in determining the appropriate regulatory controls for this software in the interest of public health while supporting continued innovation and development of safe medical device software.

Generally medical purpose software [1]

consists of:

(1) software in a medical device (sometimes referred to as "embedded" or "part of");

(2) software as a medical device (SaMD).

This guideline is drafted based on currently available IMDRF documents on Software as Medical Devices and published guidelines from global agencies including European Union, Health Canada and US FDA with focus on the recent developments in regulation of SaMD.

[1] Software used to make or maintain a device (testing, source code management, servicing, etc.) is not considered software with a medical purpose.

2. Definitions

2.1 Software in a Medical Device: A software application that is embedded in or is a part of dedicated hardware medical devices and achieves its intended medical purpose together with the hardware medical device.

- Is used as an accessory to a regulated medical device; or
- Transforms a mobile platform into a regulated medical device.

2.2 **Software as a Medical Device:** The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

NOTES:

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms[2]
- "without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose;
- Software does not meet the definition of SaMD if its intended use is to drive a hardware medical device.
- SaMD may be used in combination (e.g., as a module) with other products including medical devices;
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- Mobile apps that meet the definition above are considered SaMD.

2.3 **Medical purpose:** The following two terms as defined in AHWP/WG2-WG1/F001:2016 (*italicized below*) identify medical purpose applicable to SaMD:

2.3.1 **Medical Device**:

"Medical device"means any instrument, apparatus, implement, machine, appliance, implant, reagent, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability ,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

2.3.2 **In Vitro Diagnostic (IVD) medical device:**

'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body , including blood and tissue donations, solely or principally to provide information:

- concerning a physiological or pathological state;
- concerning a congenital abnormality;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

This includes kits, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus , systems or other articles.

Note: Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for a particular in vitro diagnostic examination.

2.3.3 Additional considerations for SaMD

SaMD may also:

- provide means and suggestions for mitigation of a disease;
- provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities;
- be an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

2.4 **Intended Use / Intended Purpose:** The term "intended use / intended purpose" is the objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. To simplified the representation, the term "Intended used" will be used throughout the document.

3. Classifying medical device software as Medical Devices

Medical device software (covers both software in a medical device and software as a medical device) that fall under medical device definition will be regulated as medical devices. It is noted that the medical device definitions in general encompass products intended to be used in the treatment, mitigation, diagnosis, monitoring or prevention of a disease or abnormal physical condition, as stated in section 2.3.1 of this document.

4. Forms of Medical Device Software

4.1 Medical Device related software are typically presented by the manufacturer in the following means:

a) Software that drives a medical device or influences the use of a device. This typically refers to Software in a Medical Device or embedded software, which is incorporated as a component or part of accessory of a medical device. This type of software regulates under general medical device or IVD medical device but not

SaMD. E.g. imaging software in diagnostic ultrasound system, software in pacemaker, mobile software that controls insulin pump delivery rate

b) Software that is intended to be an accessory to a medical device
E.g. Software that accepts data transmitted from medical devices

c) Software that is a medical device in its own right
Software related to the functioning of a medical device may be part of a device or a device in its own right if it is placed on the market separately from the related device.
E.g. Treatment planning software, data analysis software for the purpose of directly aiding in the treatment or diagnosis of a patient

For category (b) and (c) software that is able to perform its medical purpose without being embedded in a hardware medical device or being dependent on specific or proprietary medical purpose hardware. This would refer to software capable of running on general purpose (non-medical purpose) computing platforms. In this case it would be able to meet the definition of 'software as a medical device' (SaMD).

4.2 SaMD does not limit the supply through:

a) Physical Delivery of Removable Media (e.g. DVD, USB Flash Drive etc.)

b) Download, transfer and/or installation directly to the end-user, and may be used as an accessory to a regulated medical device, or transform a general purpose platform (e.g. mobile platform) into a regulated medical device

c) Web/Cloud-based software which is executed on a remote server through a web browser or mobile platform. A web-based software would involve the delivery of the Software as a service rather than a product.
Example: Web system or Mobile Medical Application for the monitoring of clinical data may interact with a medical device (e.g. implanted devices or homecare devices), and uses a transmitter to send the information over the internet, a landline telephone or a mobile telecommunication network.

The information is collected and stored on a web server usually run by an external party who is generally the manufacturer of the system. The information can be reached by authorized health professionals or the patient through an internet connection.

The modes of delivery for software do not affect the general principles of software qualification, classification, design verification and validation. However, manufacturer should implement effective and appropriate post-market control to ensure traceability and data integrity that relate to of end-users, including cybersecurity measures to protect the confidentiality of patient data.

5. Medical Device Software - Aspects Influencing Patient Safety

There are many aspects in an ever-increasing complex clinical use environment that can raise or lower the potential to create hazardous situations to patients. Some examples of these aspects include:

- The type of disease or condition
- Fragility of the patient with respect to the disease or condition
- Progression of the disease or the stage of the disease/condition
- Usability of the application
- Designed towards a specific user type
- Level of dependence or reliance by the user upon the output information
- Ability of the user to detect an erroneous output information
- Transparency of the inputs, outputs and methods to the user
- Level of clinical evidence available and the confidence on the evidence
- The type of output information and the level of influence on the clinical intervention
- Complexity of the clinical model used to derive the output information
- Known specificity of the output information
- Maturity of clinical basis of the software and confidence in the output
- Benefit of the output information vs. baseline
- Technological characteristics of the platform the software is intended to operate on
- Method of distribution of the software
- Any malfunction or breakdown of the software that may lead to erroneous output information

For software that are embedded in hardware devices i.e. software in medical devices, the potential hazards arising from its use and the overall safety of the software hinges largely on the hardware device and their overall intended medical purpose.
However, for SaMD where the software functions by itself, defining its functionalities and thus the intended medical purpose of the SaMD is the cornerstone in enabling the safe and effective use of the software.

6. Medical Device Software – Defining the Intended Use

The intended use for software in medical device is largely tied to the intended use of the hardware device. For standalone medical device software, the intended use statement needs to be clearly defined to enable its appropriate qualification and classification as SaMD or otherwise.

The following are the major factors that provide adequate description of the intended use of the software:

(1) Significance of the information provided by the SaMD to the healthcare decision (e.g. diagnose, treat, clinical management);
(2) State of the healthcare situation or condition (e.g. critical condition, non-serious condition); and
(3) Description of the core functionality of the software (e.g. Identify and prompt healthcare providers of potential arrhythmia episodes in cardiac patients based on their ECG recording).

When these above factors are included in the manufacturer's description of intended use for medical device software, they can be used in determining their classification as SaMD or otherwise consistently.

7. Qualification of different types of SaMD

Qualification of software in a medical device is relatively less challenging as the existing classification criteria for hardware medical devices are still relevant to these software as their intended use is largely tied to that of the hardware medical device. There is need for further clarity in the qualification and classification of standalone medical device software, which functions by themselves, independent of hardware devices.

Software form – embedded, standalone, mobile application – plays little to no role in determining whether the software is qualified as a medical device based on the medical device definition. With the enormous complexity and rapid advancements in software technology, it would be appropriate to follow suit and avoid referring to the software forms in any guidelines on software qualification to be developed. The basis of qualifying any software as SaMD relies heavily on the intended use of the software which in reality translates to the degree of risk posed by the software to the patient and/or the end-user.

Some examples of types of medical device software and their qualification are described below:

7.1 **Hospital Information Systems (HIS)/ Workflow Management Systems**

Software intended for communication and management in a clinical setting not related to patient therapy and diagnosis, such as appointment scheduling, billing and workflow management, does not perform medical purposes are therefore not qualified as medical device and SaMD.

7.2 **Electronic Health Record (EHR) or Electronic Medical Record (EMR)**

Information systems for HER/EMR that only intended to store and view patient information (for example: age, weight, notes about a patient's appointment, patient test results, order processing, scheduling, or managing patient movement) would not be subject to medical device regulation. These are such software types that simply act to replaces a patient's paper file. However, additional modules in such systems that are intended to provide additional information that contributes to diagnosis, therapy and follow-up would be regulated as SaMD.

7.3 **General well-being systems**

Information systems that are simply sources of general information, i.e. providing general health advice to health professionals or consumers. In addition, software intended for developing or maintaining general fitness, health or wellness of persons, without specific intention for the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease that considered as Medical

Purpose as outlined in these documents, are not regulated as medical devices and SaMD.

7.4 **Communication Systems**

7.4.1 **For patient monitoring**

Communication Systems intended for active patient monitoring may qualified as medical devices or SaMD, depends on what information are collected, exchanged and communicated to.

7.4.2 **For controlling medical devices**

Communication software that connects / information exchange to an existing device software (control system) for purposes of controlling a medical device's operation, functions are regulated as medical devices or SaMD. Such as software for performing tele-surgery, wireless remote controls or synchronization devices for computed tomography (CT), X-Ray machines, infusion pumps.

7.4.3 **Middleware**

Software that connects two or more software application to enable connectivity only without performing any medical purposes is not considered as medical device or SaMD.

7.4.4 **PACS (Picture archiving and communication system)**

Software that stores and transport medical image. Some system supports simple viewing function.

7.5 **Decision Support Software**

Decision support software, with their role in provide additional information that contributes to diagnosis and therapy are qualified as medical devices. Such software may combine medical knowledge databases and algorithms with patient specific data, or suggest treatments for specific patient conditions. This would include radiotherapy treatment planning systems that calculate ionizing irradiation dosage, drug or chemotherapy planning systems and computer aided detection systems that automatically read x-ray images or interpret ECG. As such software would indeed

directly influence in the treatment and diagnosis of the patient, such software would fit into the medical device definitions and SaMD definition if it is installed in a general purpose computing platform or mobile platform without driving a hardware medical device.

The comparison of types of software that are regulated as Medical Device among some of the global regulatory agencies is presented in Annex 1 of this document.

8 References

[1] IMDRF/SaMD WG/N10FINAL:2013: Software as a Medical Device (SaMD): Key Definitions

[2] AHWP/WG2-WG1/F001:2016 Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”

[3] GHTF/SG1/N71:2012: Definition of Terms Medical Device and In Vitro Diagnostic Medical Device

[4] GHTF/SG1/N77:2012: Principles of Medical Device Classification

[5] IMDRF/SaMD WG/N12FINAL:2014: “Software as a Medical Device”: Possible Framework for Risk Categorization and Corresponding Considerations

[6] IMDRF/GRRP WG/N52 FINAL:2019 “Principles of Labelling for Medical Devices and IVD Medical Devices”

[7] EU, MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, October 2019

[8] EU, MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC, April 2020

[9] EU, MDCG 2021-24 Guidance on classification of medical devices, October 2021

[10] Health Canada, Software as a Medical Device (SaMD): Definition and Classification, 2019

[11] Health Canada, Guidance Document: Software as a Medical Device (SaMD): Classification Examples, 2022

[12] US FDA, Step 2: Is the Software Function Intended For Administrative Support of a Health Care Facility? https://www.fda.gov/medical-devices/digital-health-center-excellence/step-2-software-function-intended-administrative-support-health-care-facility

[13] US FDA, What are examples of Software as a Medical Device? https://www.fda.gov/medical-devices/software-medical-device-samd/what-are-examples-software-medical-device
[14] US FDA, Medical Device Data Systems, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-data-systems
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[16] US FDA, Policy for Device Software Functions and Mobile Medical Applications, 2022
[17] US FDA, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, 2022
[18] US FDA, General Wellness: Policy for Low Risk Devices, 2019

Annex 1: Summaries of Software types and their current qualification as medical devices in European Union, Health Canada and United State Food and Drug Administration

Software type	Hospital Information Systems (HIS) / Workflow Management System	Information Systems				Laboratory Information Systems (LIS) and Work Area Managers (WAM)	Communication Systems (Tele-medicine)				Mobile apps that transform mobile platforms into medical devices	Web Systems for monitoring of data (Device Monitoring)		Decision Support Software / Expert System (EU IVDR) / Interpretation of raw data (EU IVDR)		Automate tasks for health care providers	General fitness, health or wellness
		Medical Device Data System	Patient management/ information (US) / Home care monitoring (EU)	Access electronic/ public health records	Additional modules in Electronics Patient Record for diagnosis, therapy and follow-up		Any Platform										
Intended use – EU Interpretation	Patient admission, scheduling patient appointments, insurance and billing purposes		Intended for archiving patient results or for transferring results from home to healthcare provider. Results are available, readable and understandable by the user without the intervention of the software.	Store & transfer electronic patient records. Archive all kinds of documents & data related to a specific patient (e.g. vital parameters, patient identification, scheduling, examination results, image identification details & other documented clinical observations. - *Clinical Information Systems (CIS)/ Patient Data Management Systems (PDMS)* - *Pre-hospital ECG System*	Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up, e.g. - *Image viewer with functionality for diagnosis* - *Medication module* - *Generate alarms* - *Provide information to start patient's treatment to paramedics when patient is transported*	Support the process from patient sample to patient result. Management & validation of incoming information from IVD analysers (e.g. calibration, QC, product expiry, feedback) through interconnection with various analytical instruments. Takes care of communication of data (results, statistics) to external databases. Results are available, readable and understandable without the intervention of the software.		General communication systems (email, mobile, video, paging etc.) for general purposes - *Home care monitoring* - *Video appointment*	Telesurgery software - intended to conduct a surgical procedure from a remote location. Remote control software used in combination with telesurgery robots.			Monitoring of non-medical performance of medical devices (software monitoring medical devices in hospital for maintenance & report)	Monitoring of performance of medical devices	MDR: Computer based tools which combine medical knowledge databases and algorithms with patient specific data *e.g. Radiotherapy treatment planning systems (calculate ionizing irradiation dosage), drug/chemotherapy planning systems (calculate drug dosage administration) & Computer aided detection system (automatically analyse x-ray images or interpret ECG)* *IVDR Expert System:* capturing and analysing together one or multiple results obtained for one patient by means of in vitro examination of body samples (possibly combined with information from medical devices and non-medical devices) e.g. - Software that uses an algorithm to characterize viral resistance to various drugs, based on nucleotide sequence generated by genotyping assays IVDR Interpretation of raw data: Used to render raw data readable for the user, obtained from an in vitro diagnostic medical device by means of in vitro examination of body samples			
EU qualification	Not MD (MDR)		Not MD (IVDR)	Not MD (MDR)	**MD (MDR)** (modules only)	Not MD (IVDR)		Not MD (MDR)	**MD (MDR)**			Not MD (MDR)	**MD (MDR)**	**MD (MDR)** **MD (IVDR)**			
Intended use – HC Interpretation	Software intended for administrative support of a healthcare facility Software that enables workflow including patient registration and scheduling visits	Software products that transfer, store, convert formats, and display medical device data		Software intended to serve as electronic patient records or tools to allow a patient to access their personal health information.	Software modules within EHRs that meet the definition of a medical device												Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps
HC qualification	Not MD	Not MD		Not MD	**MD**												Not MD

Intended use – US Interpretation	Software functions intended for administrative support of a health care facility	Software functions that are solely intended to transfer, store, convert formats, and display medical device data or medical imaging data	Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions	Software functions that enable patients or health care professionals to interact with EHR systems (e.g., transfer, store, convert formats, display electronic patient records) that are certified under the ONC Health IT Certification Program, or interact with personal health record (PHR) systems			Software functions intended to generate alarms or alerts or prioritize patient-related information on multi-patient displays, which are typically used for active patient monitoring		Software functions that connect to an existing device type for purposes of controlling its operation, function, or energy source		Software functions (typically, mobile apps) that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices				Software functions that perform simple calculations routinely used in clinical practice Body Mass Index (BMI) Total Body Water / Urea Volume of Distribution Mean arterial pressure Glascow Coma Scale score APGAR score NIH Stroke Scale Delivery date estimator	Automate simple tasks for health care professionals	Software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
US FDA qualification	Not device software functions	Not device software functions	Enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)	Not device software functions			**Device software functions**		**Device software functions**		**Device software functions**				Enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)	Enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)	Not MD