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FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF SOFTWARE AS MEDICAL DEVICE

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1.0. INTRODUCTION

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, these Guidelines are hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the registration of software as a medical device (SaMD) in Ghana. These guidelines are applicable to all such devices for use in humans as well as for veterinary use, where applicable.

Medical devices constitute an essential ingredient in the provision of quality and effective health care delivery. Medical devices must be safe, effective, perform as specified and manufactured from premises that meet the codes of current good manufacturing practices (cGMPs), where applicable. An appropriate regulatory framework is, therefore, required to ensure that these are adequately assured.

Such a regulatory framework must, therefore, provide appropriate guidelines that would assist the manufacturer and/or its local agent to substantially demonstrate compliance to the applicable legislation. The manufacturer would hence be required to demonstrate: i. a functional quality management system (QMS), ii. a system for post-market surveillance, iii. a technical documentation, iv. a declaration of conformity, and v. the registration of the manufacturing facility and the medical devices.

In line with the current growth in science and technology in all spheres of human endeavour, software is playing an increasingly important and critical role in healthcare with many clinical and administrative purposes.

Software which finds application in healthcare, functions in a complex socio-technical environment that consists of software, hardware, networks, and people which often forms part of larger systems that must work in a unified manner.

Prevailing regulations for medical device software are largely concentrated on medical device software that is embedded in dedicated hardware medical devices and are focused around physical harm, transmission of energy and/or substances to or from the body, the degree of invasiveness to the body, closeness to sensitive organs, duration of use, diseases, processes and public health risk, competence of user and effect on population due to communicable diseases, etc.

Currently, medical device software is often able to attain its intended medical purpose independent of hardware medical devices. It is increasingly being deployed on generalpurpose hardware and delivered, in diverse care settings, on a multitude of technology platforms (e.g., personal computers, smart phones, and in the cloud) that are easily accessible. It is also being increasingly interconnected to other systems and datasets (e.g., via networks and over the Internet).

The complexity of medical device software, together with the increasing connectedness of systems, results in emergent behaviors not usually seen in hardware medical devices.

This introduces new and unique challenges. For example:

- Medical device software might behave differently when deployed to different hardware platforms.
- Often an update made available by the manufacturer is left to the user of the medical device software to install.
- Due to its non-physical nature (key differentiation), medical device software may be duplicated in numerous copies and widely spread, often outside the control of the manufacturer.

Furthermore, there are lifecycle aspects of medical device software that pose additional challenges. For instance, software manufacturers often:

- Have rapid development cycles,
- Introduce frequent changes to their software, and
- Deliver updates by mass and rapid distribution.

It is on the basis of the above that dedicated guidelines for the registration of software as a medical device have been developed.

It is acknowledged that in the development of these guidelines, reference was made to the following:

- a. IMDRF SaMD WG N10 / Software as a Medical Device: Key Definitions
- b. GHTF/SG1/N70:2011 “Label and Instructions for Use for Medical Devices”
- c. GHTF/SG1/N71:2012 “Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’”
- d. IEC 62304:2006 - Medical device software -- Software life cycle processes
- e. ISO/IEC 14764:2006 Software Engineering— Software Life Cycle Processes — Maintenance

These Guidelines must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, as well as any other relevant Guidelines and Regulations issued by the Food and Drugs Authority, Ghana.

2.0 Definitions

2.1 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:

- i. *SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.* ii. *SaMD is capable of running on general purpose (non-medical purpose) computing platforms.*³
- iii. *“without being part of” means software not necessary for a hardware medical device to achieve its intended medical purpose.*
- iv. *Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.*
- v. *SaMD may be used in combination (e.g., as a module) with other products including medical devices.*
- vi. *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.

2.2 Intended use / Intended Purpose

The term “intended use / intended purpose” is the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. Reference is made to GHTF/SG1/N70:2011 “Label and Instructions for Use for Medical Devices.”

2.3 Medical Purpose

The following two terms as defined in GHTF/SG1/N71:2012 “Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’” (*italicized below*) identify medical purpose applicable to SaMD:

2.3.1 Medical Device

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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,*
- *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 solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note: *IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.*

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.*
- *Aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.*

2.4 SaMD Changes

SaMD changes refer to any modifications made throughout the lifecycle of the SaMD including the maintenance phase. Software maintenance can include adaptive (e.g. keeps pace with the changing environment); perfective (e.g. recoding to improve software performance); corrective (e.g., corrects discovered problems); or preventive (e.g., corrects latent faults in the software product before they become operational faults). Examples of

SaMD changes include, but are not limited to, defect fixes; aesthetic, performance or usability enhancements; and security patches.

3.0 GLOSSARY

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

Authority: The Food and Drugs Authority, Ghana.

Conformity Assessment: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the

Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

Certified Copy: A true copy of the original document certified by a person registered to practice law in the Manufacturer's country of origin and endorsed with the legal practitioner's official stamp and signature.

Clinical Evaluation: The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

Clinical Investigation: Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.

Custom-made device: Any device made specifically in accordance with a duly qualified practitioner's written prescription which gives specific design characteristics and is intended for the sole use of a particular patient.

Label: Written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

Labelling/information supplied by the manufacturer: Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a

medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Manufacture: Includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, repackaging and labelling of medical devices.

Manufacturer: Means any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Medical Device Family: A group of medical devices that are made by the same manufacturer that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Medical Device Group: Medical device comprising a collection of medical devices, such as a procedure pack or tray, which is sold under a single name.

Medical Device System: A medical device comprising a number of components or parts intended to be used together to fulfill some or the entire device's intended functions and that is sold under a single name.

National Standard: A standard as prescribed by Ghana Standards Authority (GSA).

Objective Evidence: Information that can be proved true based on facts obtained through observation, measurement, testing or other means.

Performance Evaluation: Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

Process Validation: Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

Quality System: System which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System: Management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

Recall: Any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after being aware that the device may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or may not meet the requirements of the Act or regulations.

Recognised Standards: National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Technical Documentation: Documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices.

Validation: Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

ACRONYMS

CA: Competent Authority

CAB: Conformity Assessment Body

CSDT: Common Submission Dossier Template

CTS: Common Technical Specifications

DA: Designating Authority

DoC: Declaration of Conformity

EPSP: Essential Principles of Safety and Performance

FDA: Food and Drugs Authority

GHTF: Global Harmonisation Task Force

GMDN: Global Medical Device Nomenclature

GMP: Good Manufacturing Practices

IFU: Instructions for Use

IMDRF: International Medical Device Regulators Forum

ISO: International Organization for Standardization

IVD: In vitro diagnostic medical device

IVDD: In Vitro Diagnostic Medical Device Directive 98/79/EC

MD: Medical Device

QMS: Quality Management System

STED: Summary Technical Documentation

TSE: Transmissible Spongiform Encephalopathy

UDI: Unique Device Identification

4.0 REQUIREMENTS

4.1 General Requirements

4.1.1 Cover Letter

All applications for registration of a software as a medical device (SaMD) shall be made by submitting a cover letter and a completed application form addressed to:

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2783
Cantonment-Accra

4.1.2 Applicant

An application for registration of SaMD can be made by a manufacturer or by an importer of the medical device. Such an applicant would be responsible for the product and all issues relating to the product, including any information accompanying the product.

A non-resident applicant would be required to appoint a local agent with the requisite mandate to represent the said applicant. The agent would be required to produce the relevant documentation including, but not limited to, a power of attorney or any other documentation, affirming his/her appointment as an agent.

4.1.3 Local Agent

A local agent is a corporate body registered in Ghana, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters relating to the registration of a medical device(s) in Ghana. The Local Agent would, among other things:

4.1.3.1 Monitor the device on the market and appropriately inform the Authority of any relevant issue relating to a registered device, including any serious manufacturing defects with the potential to endanger the safety and/or health of the patient, operator or any other person, or public health.

4.1.3.2 Facilitate communication between the applicant and the Authority on matters relating to the product.

4.1.3.3 Handle device recalls.

4.1.3.4 Provide technical support and services to users of registered device(s).

4.1.4 Classification of applications

For purposes of submission to FDA, applications are classified into three categories as follows:

4.1.4.1 New Applications for Registration

A new application for a medical device is one intended to be placed on the Ghanaian market for the first time. A separate application is required for each single medical device or a

medical device group or a medical device family or medical device system. Such a new application for registration shall include:

4.1.4.1.1 One original hard-copy and one electronic copy in a text selectable Portable Document Format (PDF) on a CD-Rom.

4.1.4.1.2 Samples of the product as per FDA sample schedule.

4.1.4.1.3 Non-refundable application fee for registration of medical devices as per FDA Fee Schedule.

4.1.4.2 Applications for Renewal of Registration

Applications for renewal of registration shall be made at least 3 months before the expiry of existing registration by submitting the following:

4.1.4.2.1 Dully filled application form for renewal of registration.

4.1.4.2.2 Samples of the product as per the FDA sample schedule

4.1.4.2.3 Non-refundable application fee for registration of medical devices per FDA Fee Schedule.

4.1.4.3 Application for Variation of a registered Medical Device

Any application for variation to a registered product shall be made in accordance with all applicable requirements in this Guideline.

Such an application should indicate any significant change(s) that could reasonably be expected to affect the safety, quality or good performance of a registered product. Significant change(s) may include, but not limited to, any of the following:

4.1.4.3.1 the manufacturing process, facility or equipment;

4.1.4.3.2 the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity,

safety and sterility of the device or of the materials used in its manufacture;

4.1.4.3.3 the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and

4.1.4.3.4 the intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device, and any change to the period used to establish its expiry date.

4.1.4.4 The requisite variation fee per the FDA Fees Schedule shall be paid.

4.1.5 LANGUAGE

All applications and supporting documents shall be in the English language and legible. Reports submitted only in a language other than English will not be accepted.

Where a material is not originally in English, a copy in the original language and a full translation into English should be submitted. The accuracy of the translation is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Ghana Embassy or by the National Regulatory Authority of the country from where the document originates.

4.1.6 DATA PRESENTATION

All printed materials submitted including any information, data, tables, diagrams, and attachments must be legible of font size 12 or more and

FDA/MCH/MDD/GL-RSAMD/2017/03 shall be presented on A4 and 80g/m² paper. All pages shall be numbered sequentially with the format page numbered as **page x of y**, with a 'Table of Contents' indicating the sections and page numbers in the relevant sections of the application form.

Where applicable, acronyms and abbreviations should be defined the first time they are used in each part.

Dossiers should be securely **bound** and **arranged** sequentially and could be submitted in separately bound volumes for the different parts but shall be numbered serially (e.g. volume 1 of 2) for ease of reference. The dossier covers shall be made of a material which is thick and hard enough not to collapse in standing position.

Before submitting the completed form, check to ensure that all information requested for have been provided in full.

4.1.7 AN OUTLINE OF THE EVALUATION PROCESS

4.1.7.1 Receiving of new applications

An application consists of documentation in hard copies and electronic copy (a summary of the dossier contents), samples and fees. An application may only be received by FDA upon payment of the application fees.

4.1.7.2 Evaluation process

The evaluation of applications is done on a first-in-first-out (FIFO) basis unless the product meets the requirement for expedited review process as set out below.

An application may be expedited if the product is for:

4.1.7.2.1 Public health programmes. These include HIV/AIDS, Malaria, Tuberculosis,

Diseases e.g. Buruli Ulcer, and any other disease condition that may be determined by the FDA from time to time.

4.1.7.2.2 Pediatric programmes.

4.1.7.2.3 Ministry of Health tender purposes only.

4.1.7.2.4 Post approval variation.

4.1.7.2.5 Renewal of registration.

The evaluation report produced by the evaluator is peerreviewed by a second evaluator. The FDA reserves the right to request for any additional information to establish the safety, quality, and good performance of medical devices.

During evaluation, additional data and/or samples may be requested for, through a deferral letter. Once a query has been issued to the applicant the evaluation process stops until FDA receives a written response to the query. Further processing of the application may only be made if responses to queries issued in the same deferral letter contain all outstanding information requested in one submission.

Failure to comply with this condition, or if the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application will be rejected.

In the event the responses to the queries are not submitted within twelve (12) months from the date they were issued, it will be considered that the applicant has withdrawn the application.

Thereafter, registration of the product may only be considered upon submission of a new application.

4.1.7.3 Review of application by Product Registration Committee. All documentation dealing with the application including reports of

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label review, dossier evaluation, and laboratory analysis reports will be presented to the Registration Committee for review and final determination of the status of the application. The decision might be either to grant, reject or defer the application.

In the event that there are safety, quality or performance issues to be resolved as per the decision of the Committee, the application may be deferred pending resolution of the issues. Should the applicant fail to provide the required data within twelve months, it will be considered that the applicant has withdrawn the application. Thereafter, registration of the product may only be considered upon submission of a new application.

4.2 Specific Requirements

4.2.1 Manufacturer's Obligation

4.2.1.1 A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements.

4.2.1.2 A manufacturer shall keep objective evidence to establish that the medical device meets those requirements.

4.2.3.2 Manufacturing process of the Finished Product

- a. Release specification
- b. Shelf-life Specification

4.2.3.3 Finished Product

- a. Specificity
- b. Sensitivity
- c. Accuracy
- d. Stability - Justification of Shelf-life

4.3 SaMD Categorization

This section provides an approach to categorize SaMD based on the factors identified in the SaMD definition statement.

4.3.1 Categorization Principles

The following principles are necessary in the categorization approach of SaMD.

- a. The categorization relies on an accurate and complete SaMD definition statement.
- b. The determination of the categories is the combination of the significance of the information provided by the SaMD to the healthcare decision and the healthcare situation or condition.
- c. The four categories (I, II, III, IV) are based on the levels of impact on the patient or public health where accurate information provided by the SaMD to treat or diagnose, drive or inform clinical management is vital to avoid death, long-term disability or other serious deterioration of health, mitigating public health.
- d. The categories are in relative significance to each other. Category IV has the highest level of impact, Category I the lowest.
- e. When a manufacturer's SaMD definition statement states that the SaMD can be used across multiple healthcare situations or conditions it is categorized at the highest category according to the information included in the SaMD definition statement.
- f. When a manufacturer makes changes to SaMD, during the lifecycle that results in the change of the definition statement, the categorization of SaMD should be reevaluated appropriately. The SaMD is categorized according to the information included in the changed (new) SaMD definition statement.
- g. SaMD will have its own category according to its SaMD definition statement even when a SaMD is interfaced with other SaMD, other hardware medical devices, or used as a module in a larger system.

4.3.2 SaMD Categories

State Healthcare	of or	Significance of information provided by SaMD to healthcare decision
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situation condition	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

5.0 TIMELINES

All new applications and applications for renewal would be processed within a minimum period of six months, unless:

- 5.1 The application is for expedited review as specified above 3.1.7.2.1 to 3.1.7.2.4 where the process would be shorter; or
- 5.2 Where queries have been raised for the attention of the applicant, which queries have not been addressed or not been addressed adequately, for which reason the process would be longer.

6.0. SANCTIONS

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, of the Public Health Act, 2012, Act 851, which shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

- 6.1 Suspension of the processing of a pending product registration application.
- 6.2 Suspension of the processing of a pending manufacturing license application.
- 6.3 Suspension of the processing of a pending import/export license application.
- 6.4 Cancellation of the following:
 - 6.4.1 a product registration
 - 6.4.2 an import/export license
 - 6.4.3 a manufacturing license
- 6.5 Payment of administrative charges as per S 147 (2) Of Act 851. The amount would be as specified in the existing L. I. on Fees and Charges.

7.0. PENALTIES

In line with the provisions of Section 129, Part 7, of the Public Health Act, 2012, Act 851, a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of

7.1 not less than seven thousand five hundred (7,500) penalty units and not more than fifteen thousand (15,000) penalty units, or

7.2 to a term of imprisonment of not less than fifteen years and not more than twentyfive years, or

7.3 to both.

8.0 APPENDICES

APPENDIX I - LABELLING REQUIREMENTS

The label of the medical device shall have a labelling information which shall be in English and shall be expressed in a manner which is legible, permanent and in a prominent manner, and which can be easily understood by the intended user.

1. The labelling information should include the following:

- (a) the name of the device, both 'proprietary' and 'common'.
- (b) the name and address of the manufacturer
- (c) the manufacturing site address
- (d) the identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device family or medical device group family
- (e) in the case of a Class III or IV device, the control number, otherwise the batch or lot number
- (f) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, or number of units
- (g) the expiry date of the device expressed in day, month and year
- (h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance

specifications of the device if those specifications are necessary for proper use (f) the directions for use, unless directions are not required for the safe and effective use of the device.

(k) warnings, precautions and limitations of product

(l) any special storage conditions applicable to the device

2 (a) In addition to the above requirements, where the device is for sale to the general public, the labelling information shall be set out on the outside of the package that contains the device, and must be visible under normal conditions of sale;

(b) where a package that contains a device is too small to display all the information as specified in (1) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

3. Any special information, required by a relevant and applicable standard must be provided.

APPENDIX II - DEVICE DETAILS

2.1. Name(s): State both the generic and brand names of the device.

2.2. Description: A general description on design, characteristics and performance of the device should be stated. This should include relevant information on device packaging.

2.3. Category: Where applicable, provide the GMDN category of the device. Otherwise, specify any other applicable codes.

2.4. Intended Use/Indication: State the intended use of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate. The description of the target patient population for which the device is intended should also be included.

2.5. Instruction for Use: A summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed should be provided.

2.6. Contraindications: These are conditions under which the device should not be used.

2.7. Warnings: Provide the specific hazard alert information that a user needs to know before using the device.

2.8. Precautions: Briefly state precautions to be taken and any special care necessary for the safe and effective use of the device.

2.9. Adverse Effects: Specify all adverse and side effects associated with the device under normal conditions of use.

2.10. Alternative Use: Provide, if any, alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

2.11. Storage conditions: State the storage conditions for the device.

2.12. Recommended shelf-life (where applicable): State the recommended shelf-life of the device.

APPENDIX III - CRITERIA FOR DETERMINING SaMD CATEGORY

3.1 Criteria for Determining SaMD Category

Criteria for Category IV

i. SaMD that provides information to treat or diagnose a disease or conditions in a critical situation or condition is a Category IV and is considered to be of very high impact.

Criteria for Category III

i. SaMD that provides information to treat or diagnose a disease or conditions in a serious situation or condition is a Category III and is considered to be of high impact.

ii. SaMD that provides information to drive clinical management of a disease or conditions in a critical situation or condition is a Category III and is considered to be of high impact.

Criteria for Category II

i. SaMD that provides information to treat or diagnose a disease or conditions in a nonserious situation or condition is a Category II and is considered to be of medium impact.

ii. SaMD that provides information to drive clinical management of a disease or conditions in a serious situation or condition is a Category II and is considered to be of medium impact.

iii. SaMD that provides information to inform clinical management for a disease or conditions in a critical situation or condition is a Category II and is considered to be of medium impact.

Criteria for Category I

- i. SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.
- ii. SaMD that provides information to inform clinical management for a disease or conditions in a serious situation or condition is a Category I and is considered to be of low impact.
- iii. SaMD that provides information to inform clinical management for a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.

3.2 Examples of SaMD:

The examples below are intended to help illustrate the application of the framework and resulting categories.

Category IV:

- a. SaMD 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.

This example uses criteria IV.i from Section 3.1 in that the information provided by the above SaMD is used to treat a fragile patient in a critical condition that is life threatening, may require major therapeutic intervention, and is time sensitive.

- b. SaMD that calculates the fractal dimension of a lesion and surrounding skin and builds a structural map that reveals the different growth patterns to provide diagnosis or identify if the lesion is malignant or benign.

This example uses criteria IV.i from Section 3.1 in that the information provided by the above SaMD is used to diagnose a disease that may be life threatening, may require major therapeutic intervention, and may be time-sensitive.

- c. SaMD that performs analysis of cerebrospinal fluid spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children.

This example uses criteria IV.i from Section 3.1 in that the information provided by the above SaMD is used to diagnose a disease in a fragile population with possible broader public health impact that may be life threatening, may require major therapeutic intervention, and may be time sensitive.

- d. SaMD that combines data from immunoassays to screen for mutable pathogens/pandemic outbreak that can be highly communicable through direct contact or other means.

This example uses criteria IV.i from Section 3.1 in that the information provided by the above SaMD is used to screen for a disease or condition with public health impact that may be life threatening, may require therapeutic intervention and may be time critical.

Category III:

- a. SaMD that uses the microphone of a smart device to detect interrupted breathing during sleep and sounds a tone to rouse the sleeper.

This example uses criteria III.i from Section 3.1 in that the information provided by the above SaMD is used to treat a condition where intervention is normally not expected to be time critical in order to avoid death, long term disability or other serious deterioration of health.

- b. SaMD that is intended to provide sound therapy to treat, mitigate or reduce effects of tinnitus for which minor therapeutic intervention is useful.

This example uses criteria III.i from Section 3.1 in that the information provided by the above SaMD is used to treat a condition that may be moderate in progression, may not require therapeutic intervention and whose treatment is normally not expected to be time critical.

- c. SaMD that is intended as a radiation treatment planning system as an aid in treatment by using information from a patient and provides specific parameters that are tailored for a particular tumor and patient for treatment using a radiation medical device.

This example uses criteria III.ii from Section 3.1 in that the information provided by the above SaMD is used as an aid in treatment by providing enhanced support to the safe and effective use of a medical device to a patient in a critical condition that may be life threatening and requires major therapeutic intervention.

- d. SaMD that uses data from individuals for predicting risk score in high-risk population for developing preventive intervention strategies for colorectal cancer.

This example uses criteria III.ii from Section 3.1 in that the information provided by the above SaMD is used to detect early signs of a disease to treat a condition that may be

lifethreatening disease impacting high-risk populations, may require therapeutic intervention and may be time critical.

- e. SaMD that is used to provide information by taking pictures, monitoring the growth or other data to supplement other information that a healthcare provider uses to diagnose if a skin lesion is malignant or benign.

This example uses criteria III.ii from Section 3.1 in that the information provided by the above SaMD is used as an aid to diagnosing a condition that may be life-threatening, may require therapeutic intervention and may be time critical by aggregating relevant information to detect early signs of a disease.

Category II:

- a. SaMD that analyzes heart rate data intended for a clinician as an aid in diagnosis of arrhythmia.

This example uses criteria from II.ii Section 3.1 in that the information provided by the above SaMD is used to aid in the diagnosis of a disease of a condition that may be moderate in progression, may not require therapeutic intervention and whose treatment is normally not expected to be time critical.

- b. SaMD that interpolates data to provide 3D reconstruction of a patient's computer tomography scan image, to aid in the placement of catheters by visualization of the interior of the bronchial tree; in lung tissue; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery.

This example uses criteria II.ii from Section 3.1 in that the information provided by the above SaMD is used to aid in the next treatment intervention of a patient where the intervention is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- c. SaMD that uses data from individuals for predicting risk score for developing stroke or heart disease for creating prevention or interventional strategies.

This example uses criteria II.iii from Section 3.1 in that the information provided by the above SaMD is used to detect early signs of a disease to treat a condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- d. SaMD that integrates and analyzes multiple tests utilizing standardized rules to provide recommendations for diagnosis in certain clinical indications, e.g., kidney function, cardiac risk, iron and anemia assessment.

This example uses criteria II.ii from Section 3.1 in that the information provided by the above SaMD is used to detect early signs of a disease to treat a condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

Note: This example includes both serious and potentially non-serious conditions but per the categorization principle in Section 4.3.1 when a manufacturer's SaMD definition statement states that the SaMD can be used across multiple healthcare situations or condition it will be categorized at the highest category according to the SaMD definition statement.

- e. SaMD that helps diabetic patients by calculating bolus insulin dose based on carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported to adjust carbohydrate ratio and basal insulin.

This example uses criteria II.ii from Section 3.1 in that the information provided by the above SaMD is used to aid in treatment of a condition not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

Category I

- a. SaMD that sends ECG rate, walking speed, heart rate, elapsed distance, and location for an exercise-based cardiac rehabilitation patient to a server for monitoring by a qualified professional.

This example uses criteria I.ii from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- b. SaMD that collects data from peak-flow meter and symptom diaries to provide information to anticipate an occurrence of an asthma episode.

This example uses criteria I.ii from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide best option to mitigate a condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- c. SaMD that analyzes images, movement of the eye or other information to guide next

diagnostic action of astigmatism.

This example uses criteria I.i from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that noninvasive in nature.

d. SaMD that uses data from individuals for predicting risk score (functionality) in healthy populations for developing the risk (medical purpose) of migraine (non-serious condition).

This example uses criteria I.i from Section 3.1 in that the the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that even if not curable can be managed effectively and whose interventions are normally noninvasive in nature.

e. SaMD that collects output from a ventilator about a patient's carbon dioxide level and transmits the information to a central patient data repository for further consideration.

This example uses criteria I.ii from Section 3.1 in that the the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

f. SaMD that stores historical blood pressure information for a health care provider's later review.

This example uses criteria I.ii from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

g. SaMD intended for image analysis of body fluid preparations or digital slides to perform cell counts and morphology reviews.

This example uses criteria I.ii from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- h. SaMD intended for use by elderly patients with multiple chronic conditions that receives data from wearable health sensors, transmits data to the monitoring server, and identifies higher-level information such as tachycardia and signs of respiratory infections based on established medical knowledge and communicates this information to caregivers.

This example uses criteria I.ii from Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

- i. SaMD that uses hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations to self-assess for hearing loss.

This example uses criteria from I.ii Section 3.1 in that the information provided by the above SaMD is an aggregation of data to provide clinical information that will not trigger an immediate or near term action for the treatment of a patient condition that is not normally expected to be time critical in order to avoid death, long-term disability, or other serious deterioration of health.

3.3 General Considerations for SaMD

SaMD often forms part of a clinical workflow sequence in order to improve diagnosis, treatment and patient management. However, issues with the design and/or implementation of SaMD into a workflow can lead to users making incorrect choices / decisions and can cause delays in decisions being made - this may lead to adverse consequences for patients.

Developing SaMD that are safe entails identifying risks and establishing measures that give confidence that the risks are acceptable. It is generally accepted that testing of software is not sufficient to determine that it is safe in operation. As a consequence, it is recognized that confidence should be built into software in order to assure its safety.

IEC 62304 is a standard for life-cycle development of medical device software. The standard specifies a risk-based decision model, defines some testing requirements, and highlights three major principles that promote safety relevant to SaMD:

- Risk management;
- Quality management; and
- Methodical and systematic systems engineering according to best industry practices. The combination of these concepts allows SaMD manufacturers to follow a clearly structured and consistently repeatable decision-making process to promote safety for SaMD.

Further information on these major principles is provided below followed by discussion on some specific considerations in the areas of:

- Socio-technical environment
- Technology and system environments
- Information security with respect to safety

3.3.1 Design and development

Manufacturers should select and implement an adequate process for the planning, design, development, deployment, and documenting of robust and dependable software commensurate with risk - as informed by its intended purpose, reasonable foreseeable use, and the understood and defined socio-technical environment of use.

Safety needs to be addressed early in the design and development process.

Development of software in a quality-assured manner should consider the appropriate selection and implementation of system design and development methods that:

- Include a methodical and systematic development process using models, methods, architecture, and design-modelling techniques appropriate for the development language(s) and the device's intended purpose,
- Cover the various software lifecycle stages through the application of software development standards, e.g., IEC 62304, and use of software engineering guidebooks, e.g., SWEBoK guide, SEBoK guide, and
- Systematically and methodically document the design and development process (using tools as appropriate.)

3.3.2 Post Market Surveillance

Software risks can never be totally eliminated so SaMD manufacturers should continually monitor customer issues to maintain the safety level. A monitoring process should include ways to capture customer feedback, e.g., through inquiries, complaints, market studies, focus groups, servicing, etc. The inherent nature of software including SaMD allows for efficient methods to understand and capture user experiences. It is recommended that SaMD manufacturers utilize these feedback techniques to understand failure modes and perform analysis to address safety situations. It is also recommended that SaMD manufacturers extend their monitoring to automatically detect errors of the software or system, i.e. discover and recover from an error before a failure can occur.

General considerations associated with the monitoring of SaMD include:

1. Due to its non-physical nature, a SaMD may be duplicated and numerous copies widely spread, often outside the control of the manufacturer.
2. Often an update made available by the manufacturer is left to the user of the SaMD to install. Manufacturers should make sure that appropriate mitigations address any risks that arise from the existence of different versions of the SaMD on the market.
3. Incident investigations should consider any specific case or combination of use cases that may have contributed to the failure and as appropriate manufacturers should consider accident reconstruction principles, e.g., data logging, black box recorder, etc.

3.3.3 Changes

Manufacturers of SaMD are expected to have an appropriate level of control to manage changes. Due to the non-physical nature of software, a software change management process needs specific considerations to achieve the intended result regarding traceability and documentation. These specific considerations include:

- Socio-technical environment considerations
- Technology and system environment considerations
- Information security with respect to safety considerations

SaMD changes may have a significant unforeseeable effect on the healthcare situation or condition and socio-technical environment of use if not managed systematically, not only with respect to a design change in itself, but also to the impact of the changed software after it is installed and implemented.

With any product lifecycle, change is inevitable. Failures occur and may be due to errors, ambiguities, oversights or misinterpretation of the specification that the software is intended to satisfy, carelessness or incompetence in writing code, inadequate testing, incorrect or unexpected usage of the software or other unforeseen problems. An SaMD may also fail with changes to the running environment. Changes to SaMD or its operating environment can affect its safety, quality and performance.

SaMD changes refer to any modifications made throughout the lifecycle of the SaMD including the maintenance phase. The nature of software maintenance changes can include adaptive (e.g. keeps pace with the changing environment), perfective (e.g. recoding to improve software performance), corrective (e.g. corrects discovered problems), or preventive changes (e.g. corrects latent faults in the software product before they become operational faults). These changes should be clearly identified and defined with a method of tracing the change to the specific affected software.

In order to effectively manage the changes and their impact, manufacturers must perform a risk assessment to determine if the change(s) affect the SaMD categorization and the core functionality of the SaMD as outlined in the definition statement.

Changes should undergo appropriate verification and validation before being released by the manufacturer for use. Examples of software changes (some may be considered significant and others not):

- Modification to an algorithm affecting the diagnosis or therapy delivered;
- A software change that affects the way data is read or interpreted by the user, such that the treatment or diagnosis of the patient may be altered when compared to the previous version of the software; • Addition of a new feature to the software that may change the diagnosis or therapy delivered to the patient;
- A software change that incorporates a change to the operating system or change to the configuration on which the SaMD runs;
- A software change that affects clinical workflow.

3.4 Specific Considerations for SaMD

3.4.1 Socio-technical environment considerations

The term socio-technical environment concerns the SaMD's setting of use - often comprising hardware, networks, software, and people. More formally, it may be characterized into spatial (e.g., location), activity (e.g., workflow), social (e.g., responsibility), technological (e.g., devices, systems, data sources, and connections), and physical (e.g., ambient conditions) components. SaMD supplies information and/or a structure for information.

The proper and safe functioning of SaMD is highly dependent on a sufficient and common understanding of the socio-technical environment that includes the manufacturer and the user.

Manufacturers should be aware of the socio-technical environment where inadequate considerations could lead to incorrect, inaccurate, and/or delayed diagnoses and treatments; and/or additional cognitive workload (which may, over time, make clinicians more susceptible to making mistakes).

Similarly, users should also be aware of the socio-technical environment as presumed and designed for (limitations of the SaMD's capabilities) and by the manufacturer, as not being aware may lead to overreliance or other inaccurate use of the SaMD. For example: - If the user does not have sufficient skills and expertise for correct operation of the SaMD, possible inaccurate output data may not be questioned. The same may happen if the user becomes habituated and over-reliant on SaMD over time.

- The introduction of SaMD sometimes changes clinical workflows in unanticipated ways; these changes may be detrimental to patient safety.

- The user may seek alternate pathways to achieve a particular functionality, otherwise called a *workaround*. When workarounds circumvent built-in safety features of a product, patient safety may be compromised.

Considerations for the manufacturer when identifying effects/implications and appropriate measures to safety and performance of SaMD throughout the product's design, development, and installation:

- Transparency of information on limitations with algorithms, clinical model, quality of data used to build the models, assumptions made, etc. can help users question the validity of output of the SaMD and avoid making incorrect or poor decisions;
- Integrating SaMD within real-world clinical workflows (including sufficient involvement of users from all relevant disciplines) requires attention to *in situ* use and tasks to ensure appropriate use of safety features;
- SaMD (and other systems connected to the SaMD) may be configured by the user in different ways than intended or foreseen by the manufacturer;
- Though not specific to SaMD, design of the user interface including: whether designs are overly complex (e.g., multiple, complicated screens), the appropriateness of designs for the target platform (e.g., smart phone screen versus desktop monitor), the dynamic nature of data (e.g., showing information at appropriate times and for an appropriate duration);
- Though not specific to SaMD, identification of appropriate means to display information such that it is understood by the intended user (e.g., usability including regionalization parameters, language translation, and selection/display of units);
- Communicating relevant information to the user (based on the activities conducted above) for the purpose of:
 - * Enabling the user to decide whether or not the user can use the device in the organization in terms of available hardware, competence, network, required quality for data input. And, if he/she decides to do this, information necessary to do those measures in order to use it: inform users, establish different routines, obtain necessary hardware.
 - * Enabling correct installation and configuration of SaMD for appropriate integration with clinical workflows.

3.4.2 Technology and system environment considerations

Technology and system environment refers to the ecosystem where the SaMD resides, including installed systems, interconnections, and hardware platform(s). Instructions on how to verify the appropriateness of installation of and update to SaMD as well as any changes made to the system environment (e.g., hardware and software) should be provided to the user. Reliance on hardware over which the manufacturer does not have control (operating systems not designed for a medical purpose, general-purpose hardware, networks and servers, Internet, links) should be considered and addressed by the manufacturer during design and development of SaMD (for instance, by designing robust and resilient SaMD designs).

SaMDs are always dependant on a hardware platform and often a connected environment. SaMD can be affected by cross-link interconnections – both physical connections and interoperability, i.e., the seamless communication between devices, technology and people.

Disruption in the ecosystem (e.g., resulting from service disruptions, systems maintenance or upgrades, platform failures) can result in loss of information, delayed, corrupted, or mixed patient information, or inaccurate information which may lead to incorrect or inaccurate diagnoses and/or treatments. For example: an incorrect diagnosis is made after the connection to a clinical dataset was lost because the patient diagnosis data is not available.

Considerations for the manufacturer when identifying effects/implications to safety and performance of SaMD:

Connections to other systems (e.g., reliability of the connection, resilience, quality of service, access, security, load capacity of connections to other systems and connection methods, system integration)

- Presenting information to the users and system integrators about the system requirements and resultant performance of the SaMD (e.g., the effect that changes to firewall rules might have on the operation of the system)
- Hardware platform(s) - such as smart phones, PC, servers - (e.g., reliability, dependencies, and interconnections with others hardware and software);
- Operating system(s) platform - such as Windows, GNU/Linux - compatibility; and
- Modifications and changes to the SaMD integration (e.g., platform updates) may have effects on SaMD that the manufacturer did not anticipate/foresee.
- Presenting information to the users and system integrators about the system requirements and resultant performance of the SaMD (e.g., the effect that changes to firewall rules might have on the operation of the system)

- Hardware platform(s) - such as smart phones, PC, servers - (e.g., reliability, dependencies, and interconnections with others hardware and software);
- Operating system(s) platform - such as Windows, GNU/Linux - compatibility; and
- Modifications and changes to the SaMD integration (e.g., platform updates) may have effects on SaMD that the manufacturer did not anticipate/foresee.

3.4.3 Information security with respect to safety considerations

Information security may be defined as the preservation of confidentiality, integrity and availability of information.

Incorrect management or transmission of information by an SaMD can lead to incorrect or delayed diagnosis or treatment.

SaMD may be affected by particular factors relating to information security that may affect the integrity, availability, or accessibility of information output from the SaMD needed for correct diagnosis or treatment:

- SaMD are typically used by a variety of users with different access needs, e.g., restricted access or varying information security requirements
- Platforms where a SaMD is installed typically run many other software applications.
- SaMD are typically connected to the Internet, networks, databases, or servers with varying information security requirements.

Considerations for the manufacturer when identifying implications for safety and performance of SaMD:

- The SaMD information security and privacy control requirements may need to be balanced with the need for timely information availability. • Information security requires the identification and implementation of safe (and formalized) ways to store, convert and/or transmit data.
- The design should use appropriate control measures to address data integrity when common information is accessed by multiple applications and users.

Manufacturers should make it feasible for users to safely implement information security updates.

- The protection of sensitive information requires support for sufficient access control and appropriate restriction to system settings and assets for important data.
- The design should address possible adverse system interactions with the inclusion of appropriate resilience and robustness measures.
- Instructions for users related to information security should include how to safely:
 - Install SaMD in appropriate operating environments (e.g., OS, integration of other software);
 - Manage authentication mechanisms; and
 - Update security software/spyware, operating environments, and other systems and applications, etc.

APPENDIX IV - CLARIFYING SaMD DEFINITION

This Appendix provides a representative list of features and functionalities that either meet or do not meet the definition of SaMD. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying when a feature or functionality is considered to be SaMD.

4.1 Examples of software that are SaMD:

- a. Software with a medical purpose that operates on a general purpose computing platform, i.e., a computing platform that does not have a medical purpose, is considered SaMD. For example, software that is intended for diagnosis of a condition using the triaxial

accelerometer that operates on the embedded processor on a consumer digital camera is considered a SaMD.

b. Software that is connected to a hardware medical device but is not needed by that hardware medical device to achieve its intended medical purpose is SaMD and not an accessory to the hardware medical device. For example, software that allows a commercially available smartphone to view images for diagnostic purposes obtained from a magnetic resonance imaging (MRI) medical device is SaMD and not an accessory to MRI medical device.

c. The SaMD definition notes states that “SaMD is capable of running on general purpose (nonmedical purpose) computing platforms.” SaMD running on these general purpose computing platform could be located in a hardware medical device. For example, software that performs image post-processing for the purpose of aiding in the detection of breast cancer (CAD - computer-aided detection software) running on a general purpose computing platform located in the image-acquisition hardware medical device is SaMD.

d. The SaMD definition notes states that “SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software.” Software that provides parameters that become the input for a different hardware medical device or other SaMD is SaMD. For example, treatment planning software that supplies information used in a linear accelerator is SaMD.

4.2 Examples of software that are not SaMD:

a. The SaMD definition states “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”. Examples of software that are considered “part of” include software used to “drive or control” the motors and the pumping of medication in an infusion pump; or software used in closed loop control in an implantable pacemaker or other types of hardware medical devices. These types of software, sometimes referred to as “embedded software”, “firmware”, or “micro-code” are, not SaMD.”

b. Software required by a hardware medical device to perform the hardware’s medical device intended use is not SaMD even if/when sold separately from the hardware medical device.

c. Software that relies on data from a medical device, but does not have a medical purpose, e.g., software that encrypts data for transmission from a medical device is not SaMD.

d. Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, video calling is not SaMD.

e. Software that monitors performance or proper functioning of a device for the purpose of servicing the device, e.g., software that monitors X-Ray tube performance to anticipate the need for replacement; or software that integrates and analyzes laboratory quality control data to identify increased random errors or trends in calibration on IVDs is not SaMD.

f. Software that provides parameters that become the input for SaMD is not SaMD if it does not have a medical purpose. For example, a database including search and query functions by itself or when used by SaMD is not SaMD.