THE NEW REGULATION AND THE MANAGEMENT OF SOFTWARE AND APPLICATIONS

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DEFINITION OF MEDICAL DEVICE- DIRECTIVE 93/42/EEC

- **MEDICAL DEVICE**: means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

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

NORMATIVE REFERENCES

- MEDDEV 2.1/6 Qualification and Classification of stand alone software January 2012
- Recommendation-NB-MED-2_2-4_rev5 Software and Medical Devices- 2010
- MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.18 (12-2017)
- "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations- IMDRF Software as a Medical Device (SaMD) Working Group- 2014
- IEC/TR 80002-1:2009= Medical device software –Part 1: Guidance on the application of ISO 14971 to medical device software
- EN 62304:2006= Software per dispositivi medici - Processi relativi al ciclo di vita del software
- FAQ IEC62304 -2013
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff- 2002

SOFTWARE AS A MEDICAL DEVICE (IMDRF)

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.*
- *"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 purpose 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.*

QUALIFICATION OF SOFTWARE AS MEDICAL DEVICE

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.*

Whether software qualifies as a medical device depends on its intended purpose

QUALIFICATION OF SOFTWARE AS MEDICAL DEVICE

Similar software – different purpose

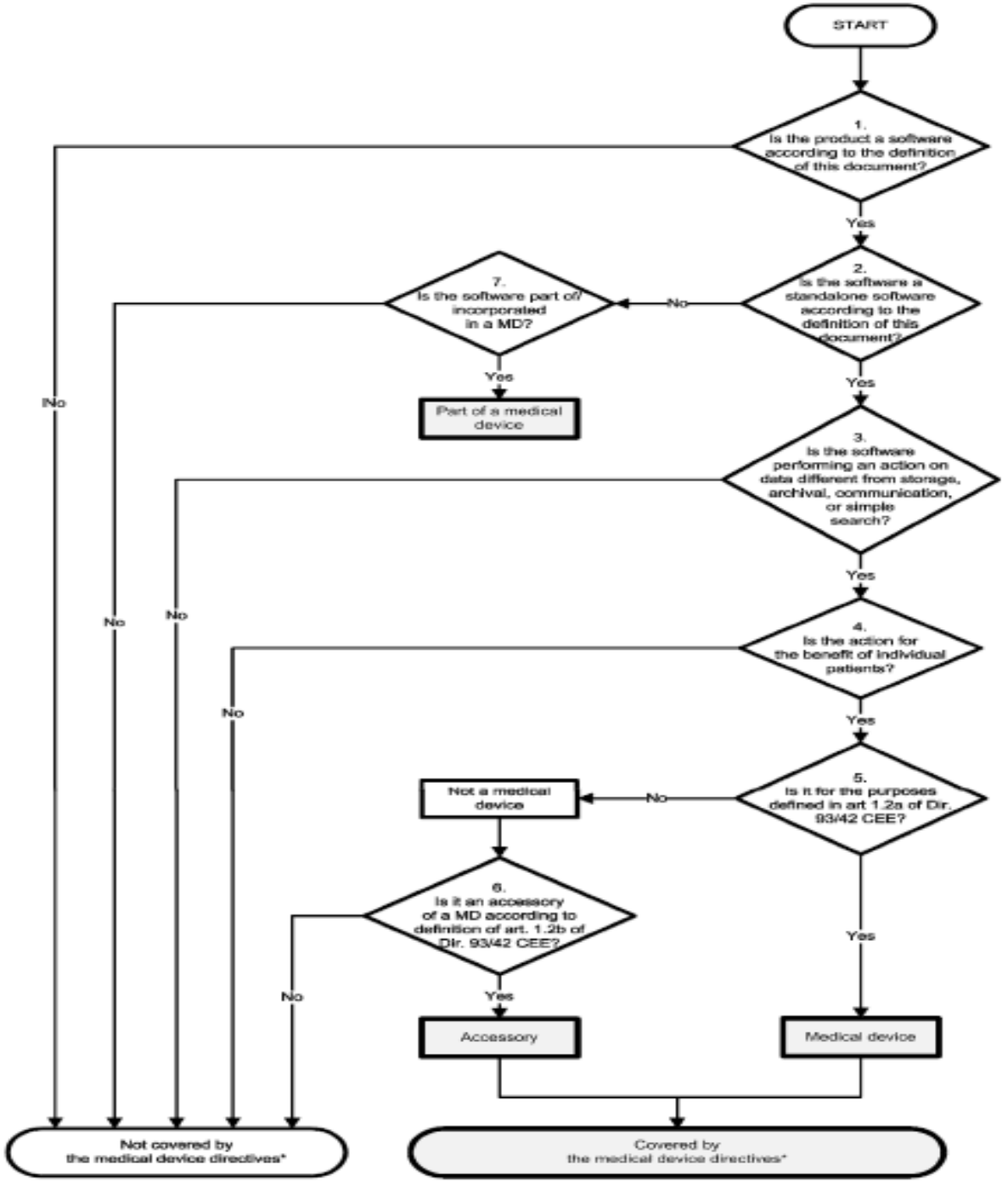
Fitness purpose

Medical purpose

QUALIFICATION CRITERIA FOR THE MEDICAL DEVICE SW

- Software can be used for a large variety of medical purposes. In that respect the arguments do not differ from those used for other medical devices.
- Stand alone software can directly control an apparatus (e.g. radiotherapy treatment), can provide immediate decision triggering information (e.g. blood glucose meters), or can provide support for healthcare professionals (e.g. ECG interpretation).
- Not all stand alone software used within healthcare can be qualified as a medical device.
- Stand alone software may run on different operating systems or in virtual environments.
- These operating systems or virtual environments do not impact the qualification criteria.
- Stand alone software might also be an accessory of a medical device.
- The risk related to a malfunction of the stand alone software used within healthcare is in itself not a criterion for its qualification or not as a medical device.
- It is, therefore, necessary to clarify some criteria for the qualification of stand alone software as medical devices

QUALIFICAT VICE SW



QUALIFICATION CRITERIA FOR THE MEDICAL DEVICE SW

Not medical devices

- To give the most recurring examples of software, which are not medical device, there are:
- Systems managing administrative patient data, like appointment scheduling, billing,
- Prescription Management Systems (but drug dose calculators using patient data like weight or body mass index are medical devices),
- Systems storing patient data, without data processing,
- Radiological Information System (RIS).

QUALIFICATION CRITERIA FOR THE MEDICAL DEVICE SW

Borderline cases

- However, even with the help of the guidances, it may be difficult to qualify software as medical device. Borderline cases exist, usually with standalone software, like software that could be used at the same time for general wellness purposes or for treatment purposes. In this case, the qualification of medical device stems from the claims in the intended use.
  For example:
- The intended use of a mobile app claims that it records and computes statistics about what the user eats and the quantities of carbs, fat, etc. It is for general wellness purposes, it is not a medical device.
- The intended use of the same mobile app (technically) now claims that it records and computes statistics about what the user eats and the quantities of carbs, fat, for diabetes management. It is for management of diabetes - an aid to the treatment of a disease - it is a medical device.

CLASSIFICATION OF THE SOFTWARE

- Each medical device shall be classified in one class: class I, class IIa, class IIb or class III. It depends on the level of risk generated by the use of the device.
- Looking at the EEC directive, it is very simple to classify software:
- Standalone software: Annex IX, §I.1.4 states that all standalone software are classified as active devices. Therefore, rules 9 to 12 of annex IX apply to your software.
- Software, which drives or influences a medical device: Annex IX, §II.2.3 states that such software falls into the same class as the device.
- The terms "drives or influence" may be interpreted. Here are some examples:
    - Software with functions modifying the state of the device actually drives it,
    - Software, which only displays data collected from the device, may not be at first sight seen as "driving" the device. But if the user uses data provided by the software to modify the state of the device, then the software "influences" the device.
    - Software, which only stores data for archiving purpose doesn't influence the medical device and may be classified alone, with rules 9 to 12 of annex IX.

CLASSIFICATION OF THE SOFTWARE- SOME EXAMPLE

Rule 9:

- Software embarked in a muscle stimulator, an incubator, a laser …
- Software connected through network (wired or wireless) to a therapeutic device. Eg: remotely monitored physiotherapy equipments,
- Radiotherapy planning system used to calculate the dose of ionizing radiation to be administered to the patient, insulin dosage planning stand alone software.

Rule 10:

- Software embarked in any scanner (ultrasound, X-Ray, MRI), an electronic thermometer …
- Software connected through network (wired or wireless) to a diagnostic device. Eg: Picture Archiving and Communication System (PACS),
- Standalone software processing patient data to allow direct diagnostic. Eg: a mobile app used to compute diagnostic data.

Remark: rule 10 is often challenging for standalone software delivering data for diagnostic or treatment purposes

CLASSIFICATION OF THE SOFTWARE- SOME EXAMPLE

Rule 11:

- Software embarked in infusion pumps, ventilators, nebulizers, suction pumps, dialysis equipment,
- Software connected through network (wired or wireless) to a device delivering or administering medicine,

Rule 12: Anything else

- Software embarked in an hospital bed
- Software used to monitor or control a class I device
- Standalone software processing patient data as an aid to diagnostic. Eg: a mobile app used to compute a score.
- All other standalone software. Use this rule with economy, when every other rule has been rejected after extensive interpretation. It may be attractive to have software on smartphones or tablets fall in rule 12. This is often not the case.

Remark: It is often difficult to make a black and white issue between rules 10 and 12, for standalone software delivering data for diagnostic purposes.

REGULATION (EU) 2017/745

The new regulation on medical devices (EU) 2017/745, published last May 5 (which will be applicable as of May 2020), emphasizing the destination criterion impressed on the software by the manufacturer, states that "**a software is in itself a medical device when it is specifically intended by the manufacturer to be used for one or more of the medical purposes established in the definition of medical device** "and that" **generic software, even if used in a healthcare setting, or software for lifestyle-related applications and well-being is not a medical device** ".

Furthermore, in order to ensure a consistent classification in all Member States, with particular regard to borderline cases, the regulation requires the Commission to decide on a case-by-case basis, on its own initiative or at the request of a Member State, whether a product or group of products falls within the definition of a medical device or not.

DEFINITION OF MEDICAL DEVICE - REGULATION (EU) 2017/745

MEDICAL DEVICE: means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

DEFINITION OF MEDICAL DEVICE

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

DEFINITION OF MEDICAL DEVICE

ACTIVE DEVICE: means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device

REGULATION (EU) 2017/745

Rule 11:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.
- Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.
- All other software is classified as class I.

ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

- 14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

[…] (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

- 17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves
- 17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

- 17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation
- 17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).
- 17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

MOBILE MEDICAL APPLICATIONS (FDA)

- ***Mobile Application (Mobile App)***

a mobile application or "mobile app" is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server

- ***Mobile Medical Application (Mobile Medical App)***

a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 4; and either is intended: - 7

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device

The intended use of a mobile app determines whether it meets the definition of a "device." As stated in 21 CFR 801.4, 5 intended use may be shown by labeling, claims, advertising materials, or oral or written statements by manufacturers or their representatives. When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

MOBILE MEDICAL APPLICATIONS

- In general, if a mobile app is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run.

MOBILE MEDICAL APPLICATIONS

Some examples of existing guidelines

- Andalusia: Complete list of recommendations on design, use and assessment of health Apps
- Catalonia: mHealth.cat
- France: Good practice guidelines on health apps and smart devices (mobile health or mHealth)
- Germany: Health apps & co: safe digital care products with clearer regulations
- United Kingdom: Guidance: Medical device stand-alone software including apps

- FDA: **Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff**

Document issued on February 9, 2015.

GRAZIE PER L'ATTENZIONE

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