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Convegno Nazionale
Associazione Italiana Ingegneri Clinici
Innovazione e accessibilità:
il governo delle tecnologie sanitarie come sfida sociale
30 AIIC 1993 - 2023

Dispositivi Medici, digitalizzazione e ICT: il ponte che non c'è (più)

Francesco Martelli

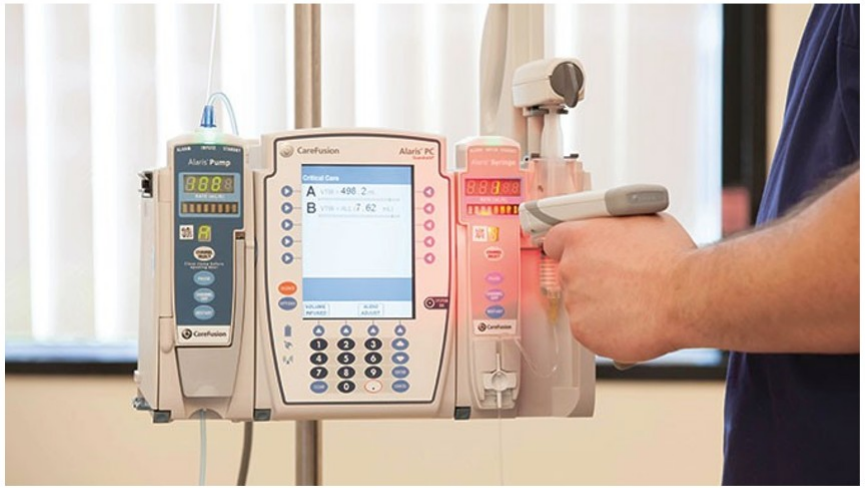
Innovation entails changes

Once upon a time, there was the Infusion Pump

- established hardware same/similar functions across
- different make/models
- standardized alarms, icons, commands
- microcontroller software, specific for the device
- no (or minimal) software update needs
- expected lifetime > 5 years without device modifications
- only routine manteinance and standardized checks required

Innovation entails changes

Things have evolved, and now we have:

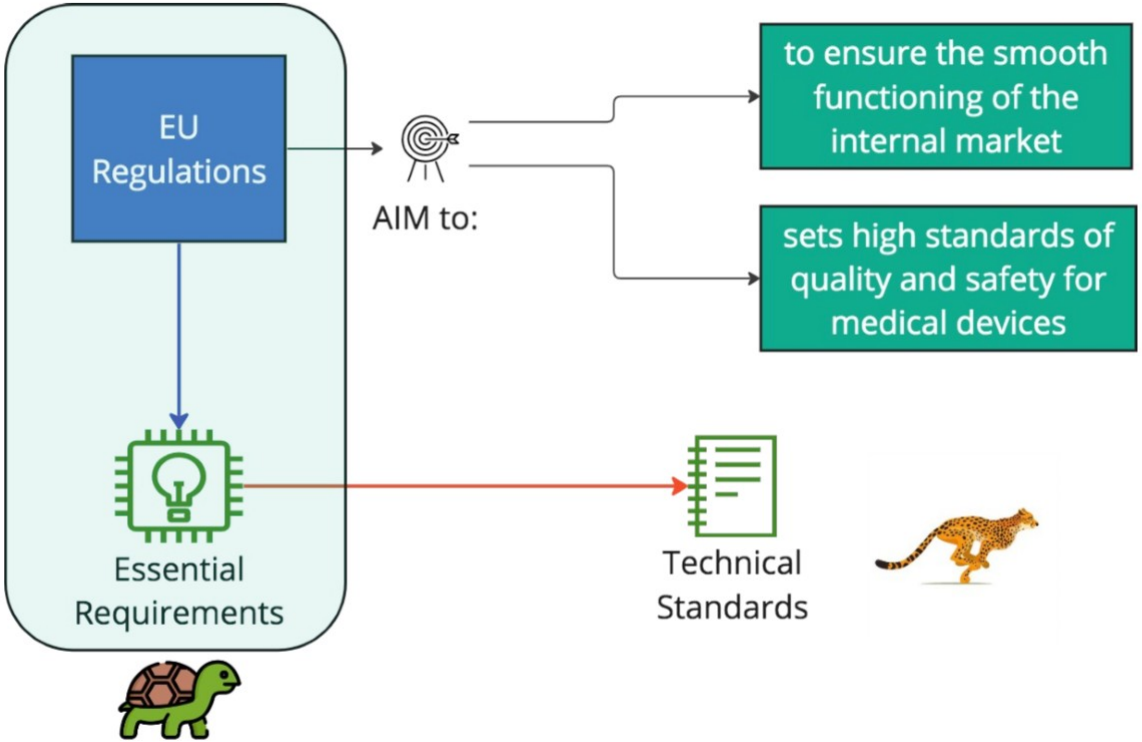


- Predetermined clinical guidelines
- Dose error reduction systems (DERSs)
- Drug libraries (with dose, volume, and flow rate)
- Risk of adverse drug interaction notifications
- Programmable Alerts (soft stops, hard stops...)
- Workflow integration: scan the drug, then the patient, then the pump to deliver the infusion.
- EHR integration: infusion tracking data sento to the medication administration records

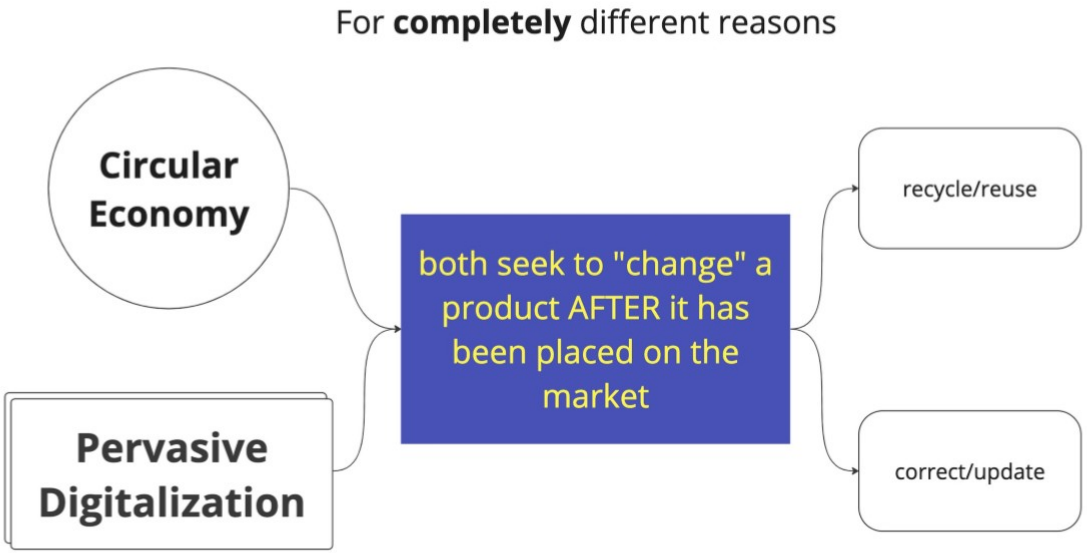
Same device, upscaled communication needs and functions

30 years of EU Regulations

Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.

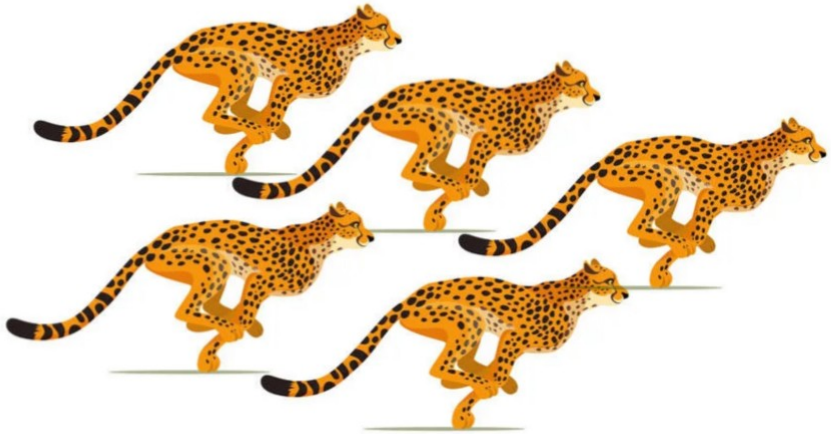


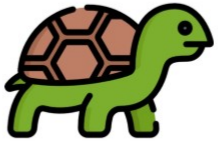
EU regulations “difficulties” (ongoing), factors 1&2 – “product changes”



EU regulations "difficulties" (ongoing), factor 3. Fast tech evolution

Some ICT technologies are evolving with a speed which is **hardly compatible** with Medical Device standards development timeframes





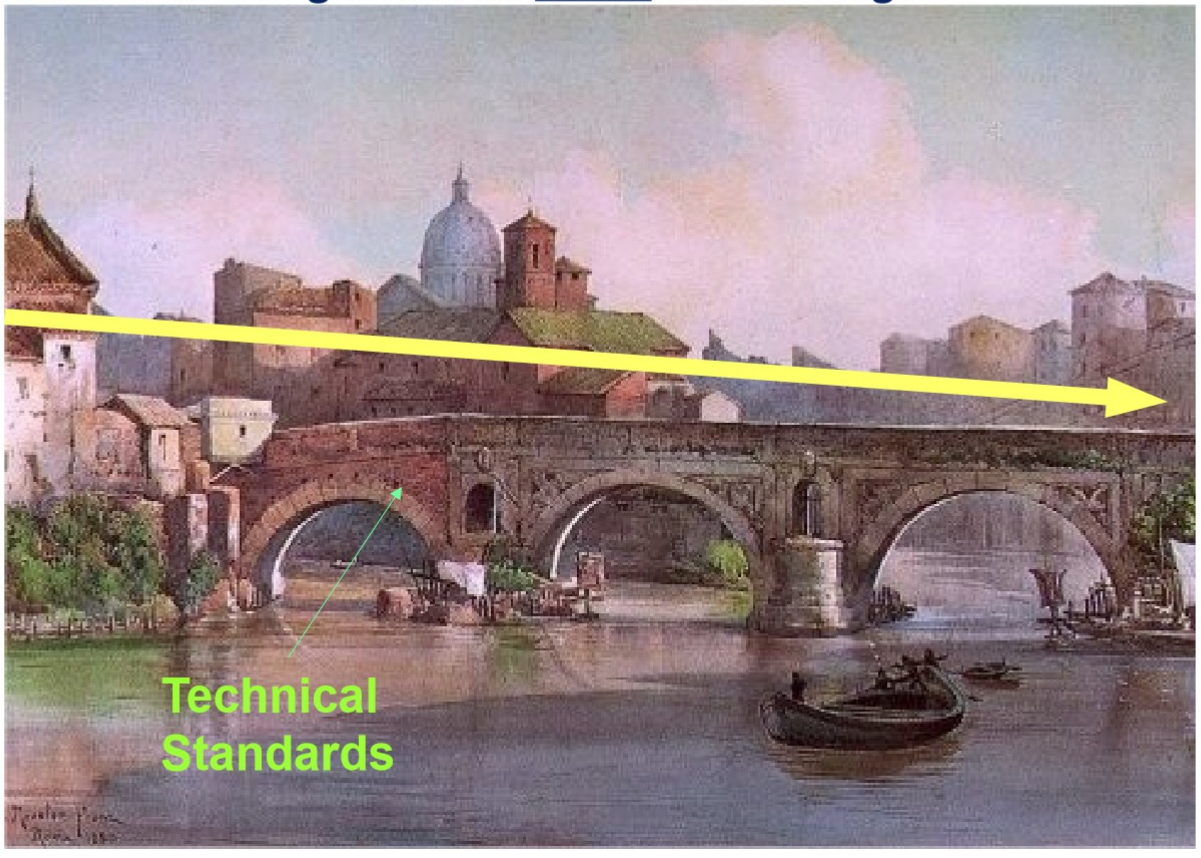
EU regulations “difficulties” (ongoing), factor 4: Med Dev & ICT standards hardly integrate

technical standards willing to rule on introduction on ICT technologies in MD world are **difficult to write** and **hardly reach a broad consensus**

IEC 62304 , “the” case

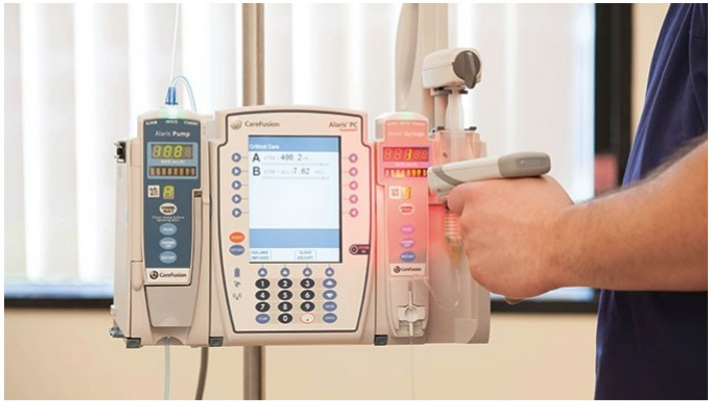
Harmonized standards and guidelines: bricks of the bridge

Essential Requirements



Product on the market

Interoperable Medical Device



MDR: Few essential requirements (GOOD)

14.1. If the device is intended for use **in combination** with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices.

14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the possible negative **interaction** between software and the IT environment within which it operates and interacts;

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the **interoperability** and compatibility are reliable and safe.

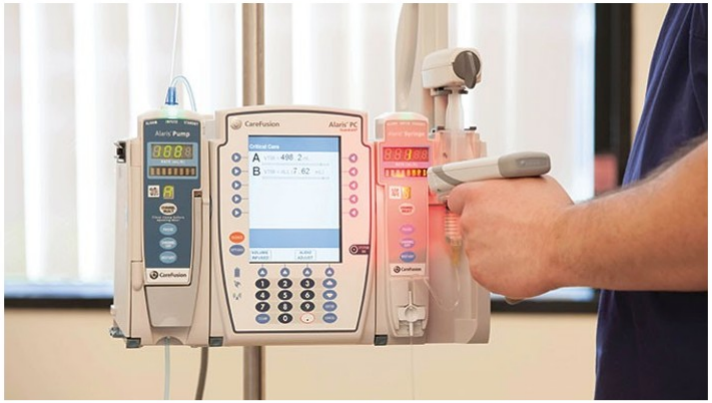
17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure **repeatability, reliability and performance** in line with their intended use. In the event of a single fault condition, appropriate means shall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

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.**

Interoperable Medical Devices



Few MD specific standards (6/25 shown), BAD

Standard	Title	Interest	93/42 Harmonized	2007/47 Harmonized	Std Req reg 745?
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes	Quality Manager/Software project manager	yes	yes	yes
ISO 14971	Medical devices — Application of risk management to medical devices	Quality Manager/Software project manager	yes	yes	yes
IEC 62304	Medical device software — Software life cycle processes	Software project manager/Quality Manager	yes		yes
EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	Software project manager/Quality Manager	yes		yes
EN 82304-1	Health Software - Part 1: General requirements for product safety	Software project manager/Quality Manager			yes
IEC 81001-5-1	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle	Software project manager and software security specialist/Quality Manager			yes
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Software project manager/usability engineering specialist/Quality Manager	yes	yes	yes

Possible reasons

Primary reason: ICT and MD world do not talk the same language, even if they are talking about interoperability

- Fundamentalist approach from the medical device community
- Focus on “industrial product”

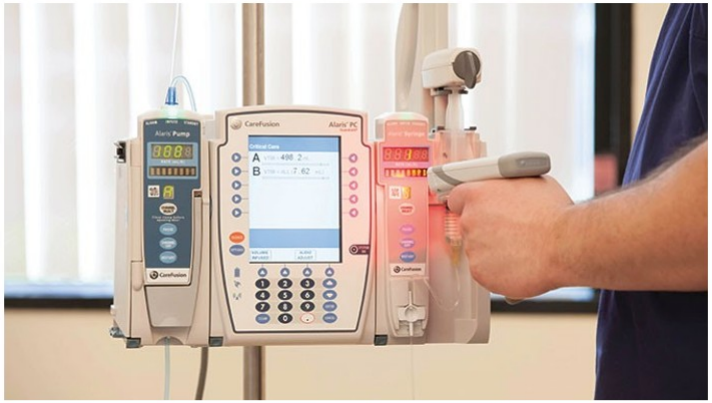
… on the other end….

ISO OBP Vocabulary

definitions of interoperability : stopped counting at **50**

definitions of sterility : **2**
state of being free from viable microorganisms
absence of viable microorganisms

Possible reasons



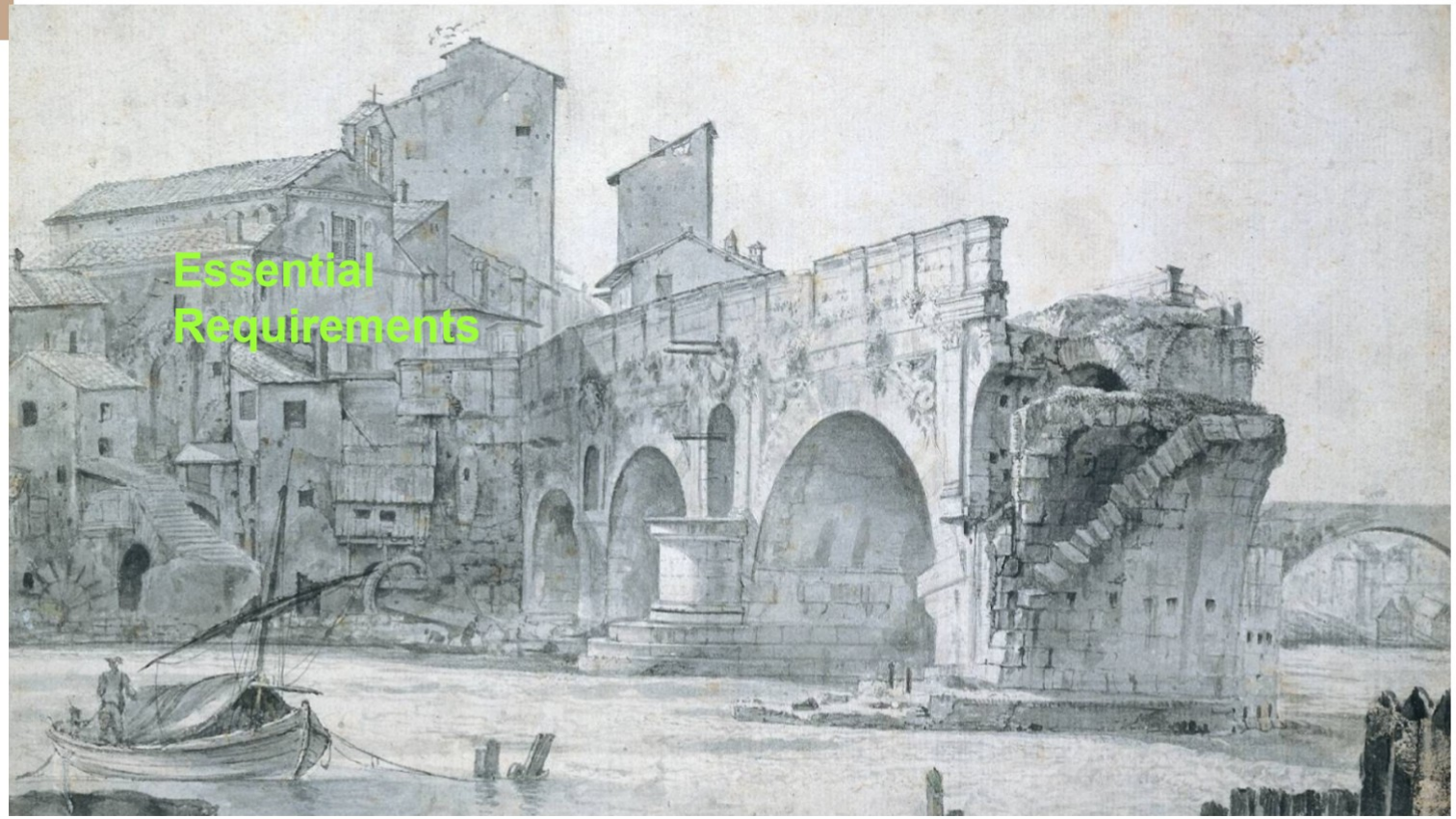
Reference	Title	Published standards	Standards under development
ISO/IEC JTC 1	Information technology	3401	482
ISO/TC 22	Road vehicles	995	213
ISO/TC 34	Food products	923	107
ISO/TC 184	Automation systems and integration	888	53

Possible reasons

Most medical software are

- extremely complex, composed by a number of components and layers
- Many of these components are frequently updated (for errors, security or functionality evolution)
- Errors and/or deviations can occur in any of the components and layers. It's difficult to check any single components, as required by MD industry
- components and layers may be **black boxes** for developers
- components and layers may be developed or/and managed OUTSIDE the "manufacturer"'s perimetry (growing phenomena)

But at the end of the day, we are simply <u>missing that bridge</u>



Product on the market

RECAP

- l'evoluzione tecnologica ha causato , in diversi settori industriali, l'introduzione del concetto che un prodotto possa **cambiare dopo la sua introduzione nel mercato** (concetto difficile da conciliare con il framework normativo europeo)

- l'ingresso della tecnologia dell'informazione e della comunicazione nel mondo dei dispositivi medici ha messo in luce **una carenza di strumenti adeguati** (standard tecnici, magari armonizzati) **per la dimostrazione della conformità ai requisiti essenziali**

New Legislative Framework "difficulties" SOLUTIONS 1

New EU COM Golden Powers

to adopt delegated acts in order to timely respond to changes (excerpt)

- Amend Annex XVI list of Products without an intended medical purpose that are subject to MDR
- Amendment of the definition of 'nanomaterial' and related definitions
- Elements to be included in the technical documentation and technical documentation on post-market surveillance
- Documentation regarding the application for clinical investigation and interventional clinical performance studies
- Tasks of expert panels and expert laboratories
- Common Specifications (CS), issued by the EU Commission in the form of Implementing Regulations, (a set of technical and/or clinical requirements for which no harmonized standard exists or is satisfactory)

New Legislative Framework "difficulties" SOLUTIONS 2

1)Because of delays in harmonization of international standards under the EU MDR and IVDR use of 'state-of-the-art ' **standards** was introduced in guidance document MDCG 2021-5

To be a real harmonized standard: Reference Published in EU OJ, Produced after a specific EU mandate, Checked by the HAS consultants (formal check?)

2)Updating of the Helsinki procedure: agreement between medical device competent authorities on borderline and classification cases

3)Frequent MDR updates (march 2023)

4)evaluation of the New Legislative Framework with consultation with stakeholders (2020) (IBM case)

New Legislative Framework "difficulties" SOLUTIONS 3

Increased use of Medical Device Coordination Group (MDCG) endorsed documents

MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	3/2020
MDCG 2019-16 rev.1	Guidance on cybersecurity for medical devices	12/2019
MDCG 2023-1	Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	1/ 2023
MDCG 2019-11	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	10/2019
Upcoming	Guidance on medical device software (MDSW)- hardware combination systems	delayed to 6 or 11/2023

...mixed feelings...

Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 - Version2 - December 2022

Smartphone application to prevent sexually transmitted infections

also allows the evaluation, through “the risk calculator” function, of the risk of infection with an STI based on sexual habit. May be a MD, since “prevents” a disease, but the risk calculation is not based on physiological parameters, therefore not a definition of medical device.

Caveat: **if the device collects (and use) physiological parameters MAY BE a MD**

Medical Calculators ARE medical devices Classification rule 11 applies, since it relates to software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, and classifies this product as atleast class IIa

Conclusioni

Grazie per l'attenzione

BONUS TRACK

FDA Approach: “hands off” <u>until I decide otherwise</u>

FDA intends to apply its regulatory oversight to those device software functions that meet the definition of a medical device and whose functionality could pose a risk to a patients safety.
For new and emerging technologies FDA uses "enforcement discretion" policies that will be in place until the FDA takes further action on each of these issues

Your Clinical Decision Support Software: Is It a Device?

FDA

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. *

Your software function must meet all four criteria to be Non-Device CDS.

Summary interpretation of CDS criteria

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.
2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).
3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.
4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

Your software function may be non-device CDS.

Non-Device Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

Device examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADe/CADx)

OR

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

OR

Device examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:

- Basis of recommendations is not provided

Your software function is a device.

***Disclaimer:** This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.


WARNING
THIS MACHINE
HAS NO BRAIN
USE YOUR OWN