

# **Regulatory, quality and clinical affairs**

NX-451 – What to know  
when working with  
medical devices

Session 12

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last update 2025-05-15

# Medical Technologies – Main Categories

## Medical Device



## AIMD

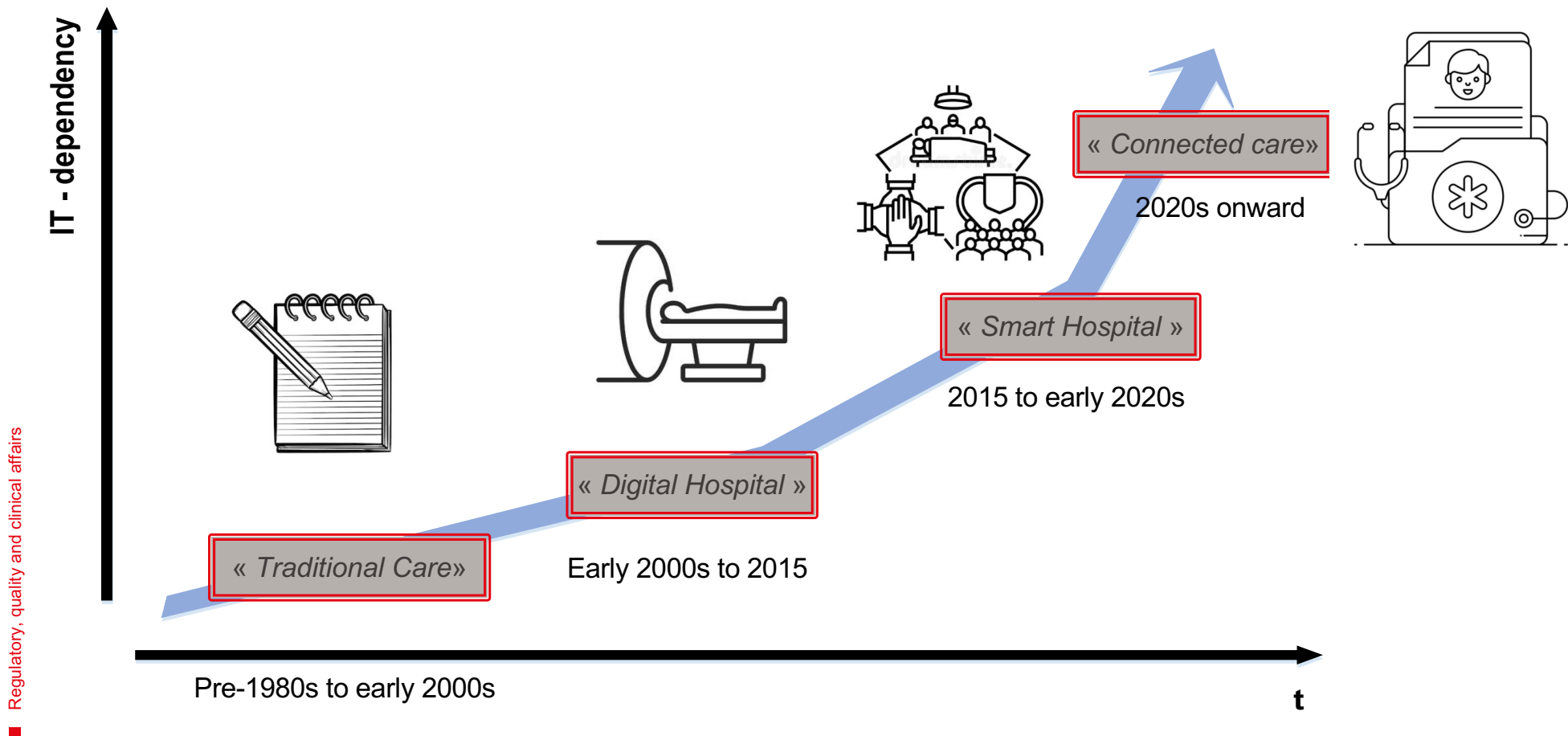


## IVD



## Software

# Software and 21<sup>st</sup> Century Medicine

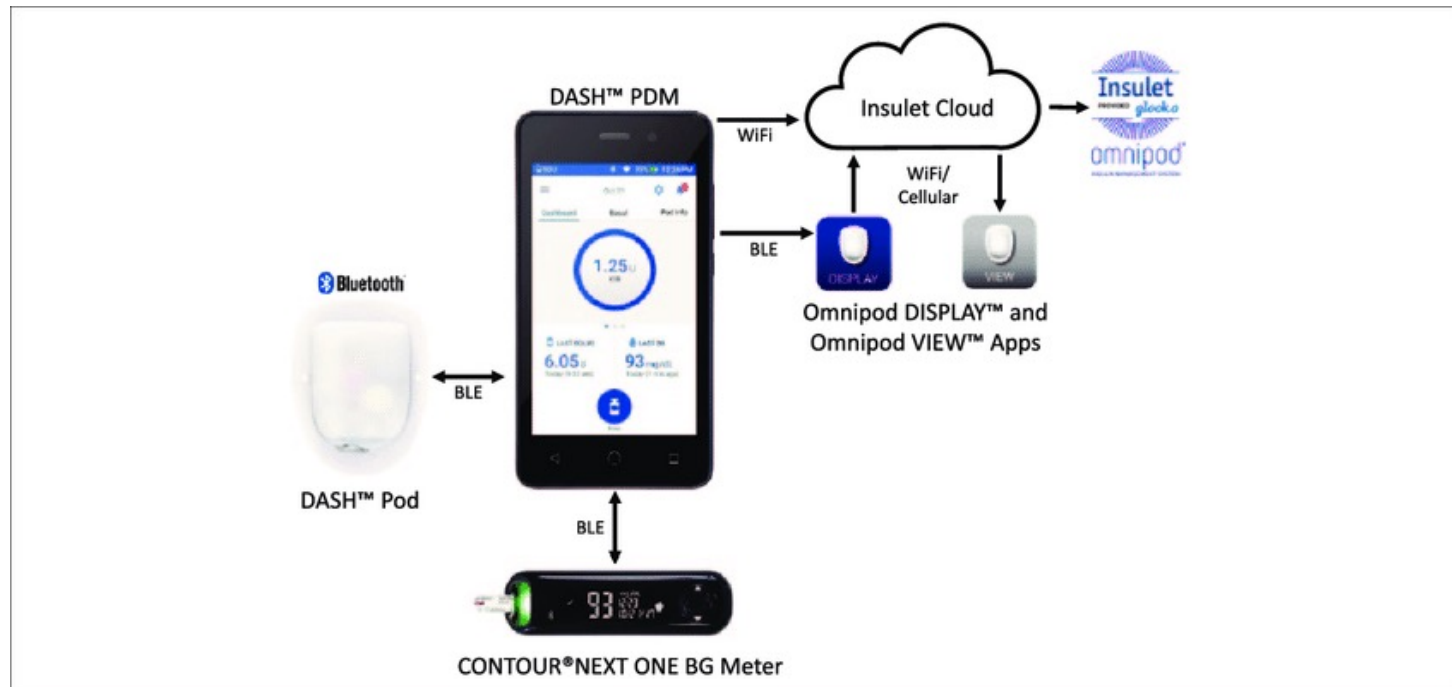


# Software and 21<sup>st</sup> Century Medicine

## Connected care – Continuous Monitoring – Leveraging wearables

The opportunity to continuously monitor patients in their daily life with sensors that measure a growing set of physiological and subjective signals and external information in smartphones, wearables and the Internet-of-Things.

Example of a connected insulin pump:

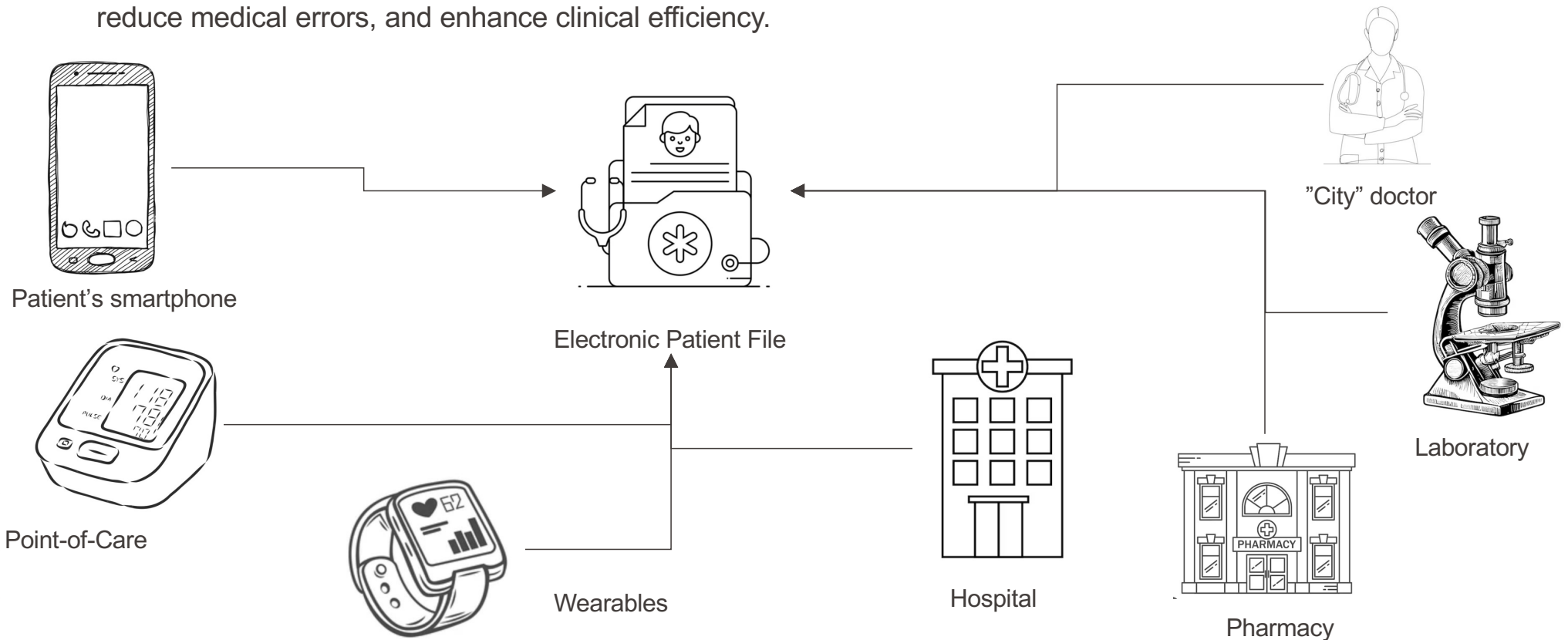


Source: <https://doi.org/10.1177/1932296818798836>

# Software and 21<sup>st</sup> Century Medicine

## Connected care – Electronic Patient File – Aggregating data sources

Electronic Patient File (EPF) is a centralized digital system that stores patients' medical histories and health information, enabling secure access and updates by authorized healthcare providers to improve care coordination, reduce medical errors, and enhance clinical efficiency.



# Software and European Innovation

Software plays a vital role in European healthcare and innovation by enabling advanced diagnostics, streamlining clinical workflows, supporting data-driven decision-making, and fostering the development of personalized and connected care solutions. Multiple technical domains are leveraged:

- **Mobile apps:** Software applications on smartphones or tablets that assist in health monitoring, diagnostics, or treatment management related to medical devices.
- **Big data:** Large and complex health-related datasets generated by medical devices, used to uncover trends, improve patient care, and support clinical decisions.
- **Deep / machine learning:** Artificial intelligence techniques that enable medical devices to analyze complex data patterns and improve diagnostic or predictive capabilities over time.
- **Internet of Things (IoT):** A network of connected medical devices and sensors that collect and exchange real-time patient data for remote monitoring and care.
- **Precision medicine:** An approach enabled by data from medical devices that tailors treatment to individual patient characteristics, such as genetics or lifestyle.
- **Companion devices:** Secondary medical devices or tools designed to work alongside primary treatments or therapies, often enhancing efficacy or monitoring outcomes.

# Software and technological evolution

The expansion of use of Software in Healthcare leads to multiple challenges...

## Rapid development of new capabilities

- Telemedicine, remote medicine
- Precision medicine
- Mobile Health



## Increasing complexity of systems to provide capabilities

- Rapid development of machine learning algorithm
- Increased use of the cloud (i.e. data storage, processing)
- Interconnectivity (App + Web front-end + multiple back-ends)



## New constraints and risk

- Rapid evolution of products
- New channels of distribution (i.e. appstore, google store, etc.)
- Patients' autonomy, increased expectations
- Data protection

# Software and technological evolution

Which in turn leads to regulatory challenges...

## Maintenance / continuity aspects

- How do I manage multiple software release per year?
- What do I report to who when there is a problem (bug fix)
- How do I distribute my software? Web download? App store?

## Security aspects

- How do I ensure compatibility / integration with hospital IT network?
- How do I control cybersecurity threats?
- How do I protect my patient's data?

## Validations aspects

- How do I validate my machine learning algorithm ?
- What is my system scope (App + Web front-end + multiple back-ends)?



# Software and Medical Device – Definition (MDR)



## MDR Article 2 – Definitions – Medical device

‘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...



If my software is a medical device, then the requirements of the MDR (or the IVDR) apply to my software...



“Medical device software” (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation. Synonym to SaMD, Software as a Medical Device.

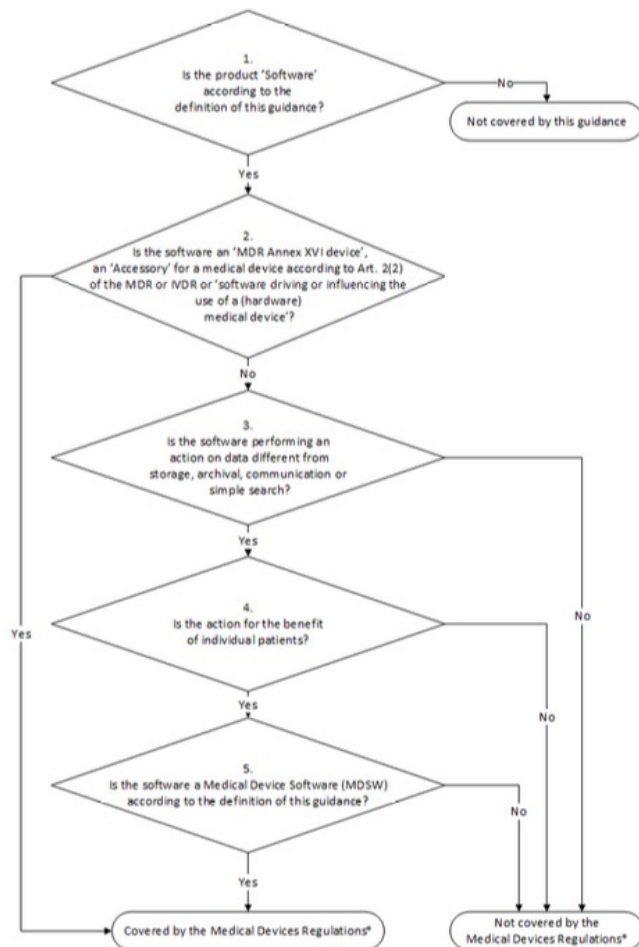
# Software and Medical Device - software type

Medical Device Software may appear in many forms:

- Software that is a component of a medical device, such as firmware, embedded software, drivers, scripts (small programs or command sequences that automate specific tasks within a medical device), and installers
- Software that is an accessory to a medical device, such as configuration tools, reading systems, or pilot/control interfaces
- Standalone software (a.k.a. “software-only devices”) that are installed on general-purpose computers to perform medical functions independently
- Apps installed on smartphones or tablets for health monitoring, diagnostics, or therapy support
- Web apps that run in the cloud or on dedicated Internet servers, providing remote access to medical services or data
- Middleware that facilitates communication and data exchange between different medical systems
- Wearable device software that collects, processes, and transmits real-time physiological data
- AI/ML algorithms embedded in or supporting medical devices, offering predictive analytics or automated interpretation

# Software and Medical Device - qualification

When my software qualifies as a medical device?



## MDCG 2019-11 Qualification and Classification of Software in MDR&IVDR

The guidance provides the following “criteria for qualification”:

1. Is the product a software?
2. Is the software an Annex XVI device or an accessory or is it influencing a medical device?
3. Is the software performing an action on data different from storage, archival, lossless compression, communication, or **simple search**?
4. Is the action for the benefit of **individual patients**?
5. Is the action for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, [...], or investigation, [...] or of a physiological process [...]?

# Software and Medical Device - qualification

If your software...

Amplify, Analysis, Evaluate, Classify, Interpret, Alarms, Calculate, Controls, Converts, Detects, Diagnose, Measures, Monitors, Guides, Decide, Correlate, Process, Supports, etc.

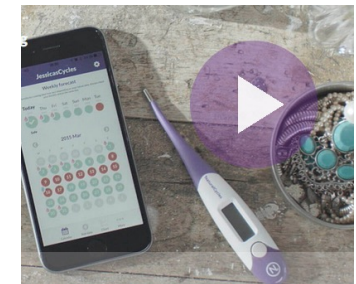
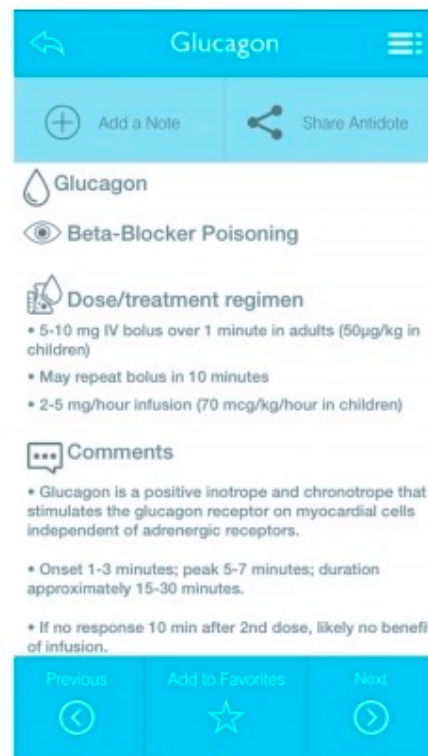
....It is likely to be a Medical Device

## Examples of Medical Devices

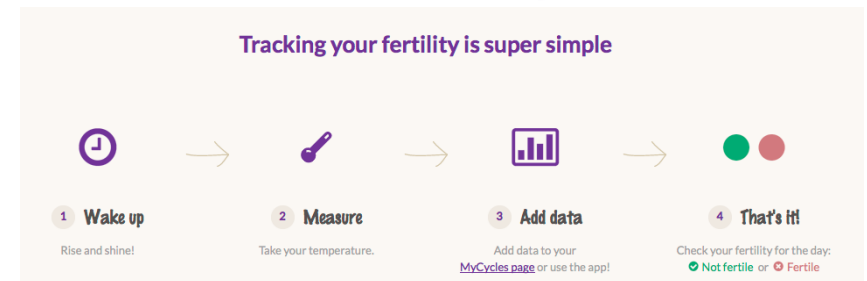
- Patient data management system with advanced functions (Interactions controls, allergies controls, ...)
- Clinical Decision Support Systems with expert functions (Drug dosing system, Radiation therapy dosing system, etc.)
- PACS (Picture Archiving and Communication System) with advanced functions (Image recognitions, measurements, analysis, etc.)
- Apps used to support clinicians (Dermato app, Measure or interpretations of ECG, Insulin pumps management app, etc.)
- Expert system to support diagnostics (decisions trees, data interpretations, etc.)

# Software and Medical Device - qualification

Are these medical devices?

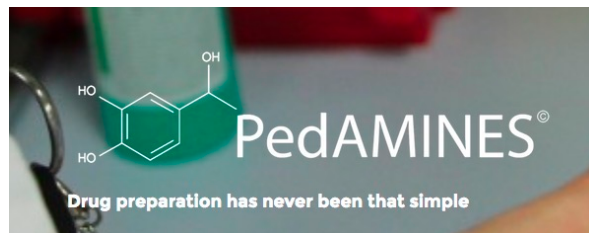









## NaturalCycles



# Software and Medical Device - qualification

Are these medical devices?



-  Enter patient's weight or age
-  Choose a drug into the drug's list
-  Follow the preparation guide step-by-step
-  Drug is ready to be delivered
-  Interact with the infusion
-  Keep historic files of all action undergone
-  Print a complete and detailed report

## WEASIS DICOM MEDICAL VIEWER





# Software and Medical Device - qualification

Are these medical devices?



# Software and Medical Device - qualification

Are these medical devices?   ChatGPT 

My knee hurts

I'm sorry to hear that your knee hurts after running. Knee pain can have several potential causes, especially after physical activity. Here are a few common reasons why your knee might hurt:

1. **Runner's Knee (Patellofemoral Pain Syndrome):** This is a common issue for runners and involves pain around the kneecap. It can be caused by overuse, improper running form, or muscle imbalances around the knee.

Can you help me narrow what it could be?

To help narrow down the cause of your knee pain after running, I'll need a bit more information about your symptoms. Here are a few questions that can guide us in figuring out the most likely cause:

1. **Location of Pain:**

- Where exactly does the pain occur? Is it around the kneecap, on the inner or outer side, or deep within the joint?

It is on the other side, the pain is quite sharp and it starts usually 1 or 2 hours after I finish my running session

Thanks for the details! Based on your description, with **sharp pain on the outer side of your knee** that starts **1-2 hours after running**, it's possible that you're dealing with **Iliotibial Band Syndrome (ITBS)**. Here's why:

Would ibuprofen help?

Yes, **ibuprofen** (an anti-inflammatory medication) can help reduce both pain and inflammation associated with conditions like **Iliotibial Band Syndrome (ITBS)**. It works by reducing swelling and easing discomfort, which may provide relief in the short term.



# Software and Medical Device - classification

## Classification rules - MDR (EU) 2017/745, Annex VIII

<b>Non invasive devices</b>	Rules 1 to 4
<b>Invasive devices</b>	Rules 5 to 8
<b>Active devices</b>	Rules 9 to 13
<b>Special rules</b>	Rules 14 to 22

The methodology to classify a device is to

1. Consider implementing rules
2. Review all the rules and justify why they are not applicable until only **one rule** is left
3. If few rules are left, choose the one with the **highest classification**

# Software and Medical Device - classification

## Implementing rules - MDR (EU) 2017/745, Annex VIII

### Combination & Accessories

- 3.2 [Devices] intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
- Accessories [...] shall be classified in their own right separately from the device with which they are used.

### Software Classification

- 3.3 Software, which drives a device or influences the use of a device, shall fall within the same class as the device.
- If the software is **independent** of any other device, it shall be **classified in its own right**.

### Applicability of multiple classification rules

- 3.5 If **several rules**, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the **higher classification shall apply**.

# Software and Medical Device - classification

## Rule 11 - MDR (EU) 2017/745, Annex VIII

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**.

# Software and Medical Device - classification

MDCG 2019-11 – Annexe III / IMDRF Guidance

State of Healthcare situation or condition	Significance of information provided by software to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	III	IIb	IIa
Serious	IIb	IIa	IIa
Non-serious	IIa	IIa	IIa

- Life threatening?
- Curable?
- Fast/moderate/slow disease progression?
- Minor chronic illness?

- Provide therapy?
- Screening?
- Detection?
- Mitigation?

- Support treatment?
- Improve safety or performance of medicinal product?
- Early prediction of disease/conditions?
- Support diff. diagnosis?

- Inform options for treatment, diagnosis, or prevention?
- Aggregate public clinical information?

# Software– MDR Requirements

- 14.2 ...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
    - ⇒ Design control, Risk Management, Cybersecurity
- 17.1 ...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**.
  - ⇒ Risk Management
- 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.
  - ⇒ Design control+ Risk Management, Cybersecurity

# Software– MDR Requirements

- 17.3 Software [...] 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 [...] and external factors...
  - ⇒ Usability + Design Control
  
- 17.4 ...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.
  - ⇒ Design Control + Cybersecurity

# Medical Device Software – How to comply?

## Compliance to GSPR

Medical Devices manufactured shall comply with the applicable requirements of the Medical Device Regulation (MDR) or the In Vitro Diagnostic Regulation (IVDR) while their product shall comply with the General Safety and Performance Requirements as defined in Annex I of these regulations



## Implement a QMS

Manufacturer shall implement a Quality Management System that define company processes.

**SAME**

## Clinical evaluation

Manufacturer shall collect and evaluate clinical data to demonstrate clinical relevance of the devices (risk / benefit ratio)

**SIMILAR**

## Prepare a Technical File

For each device manufacturer shall assemble a technical documentation that provides evidences of compliance with the requirements

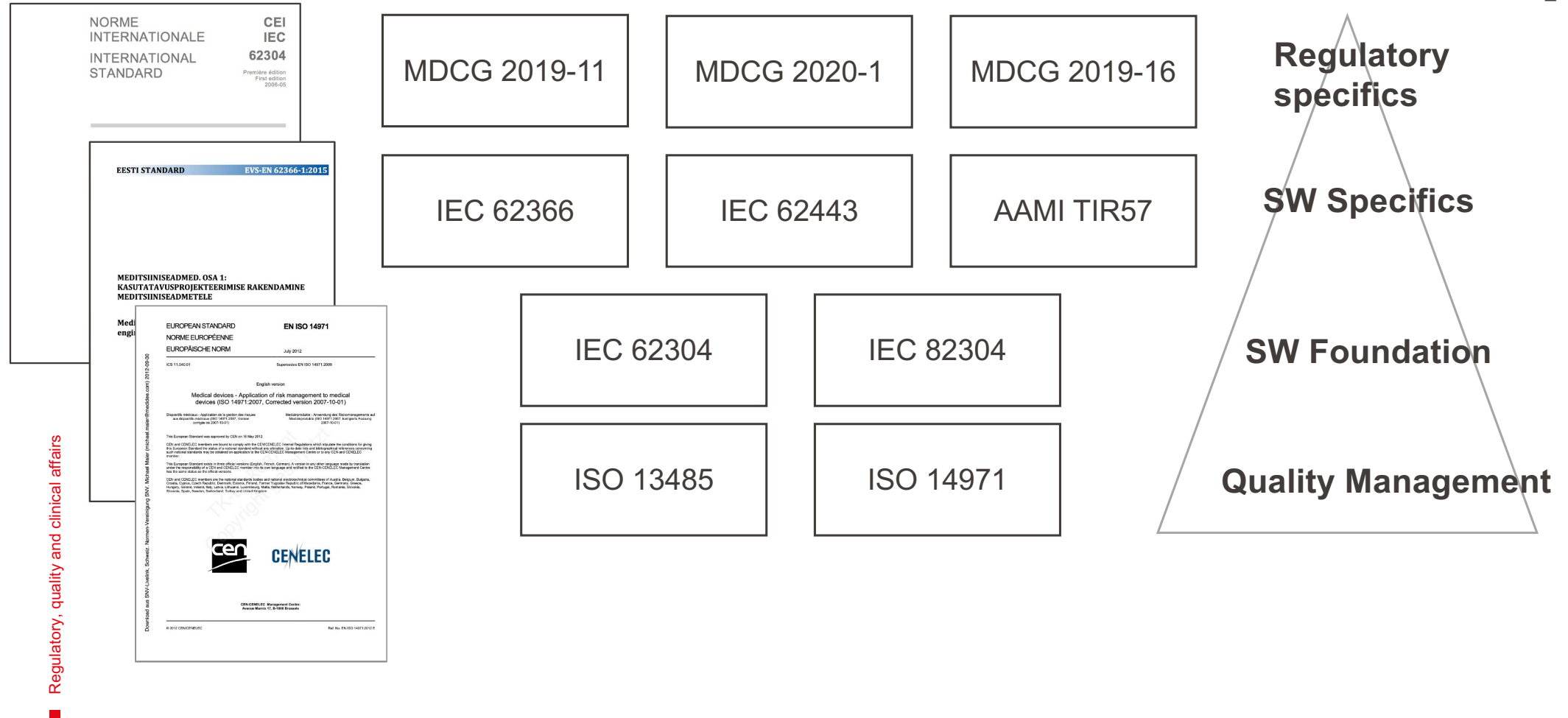
**SIMILAR**

## Conformity assessment / Notification

Depending on the situation a conformity assessment with a notified body is to be done, or an authorization for a clinical investigation is to be requested or a notification shall be performed

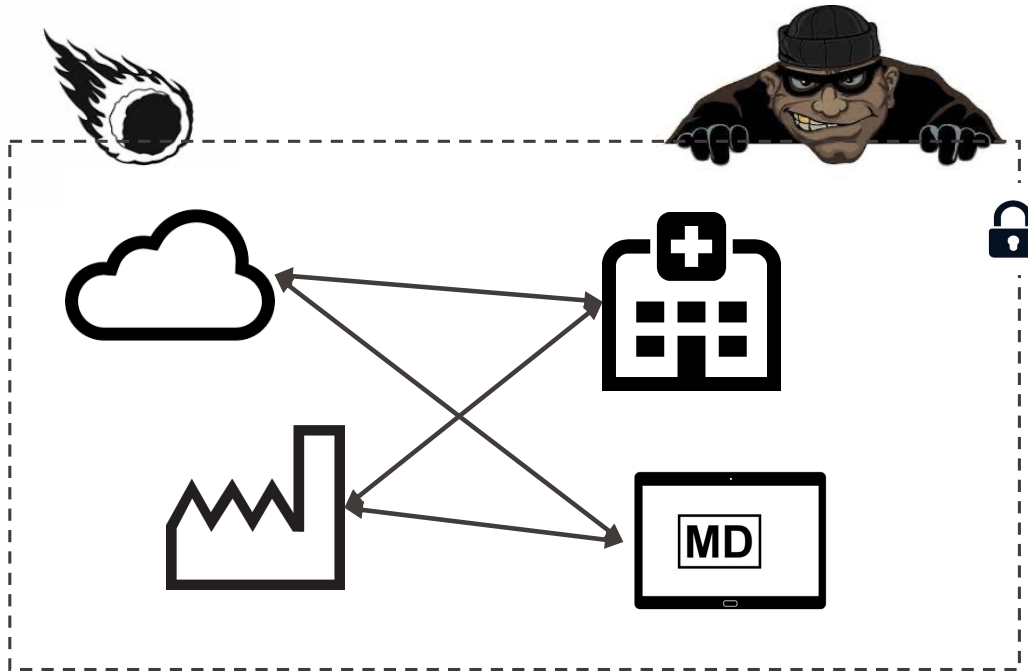
**SAME**

# Medical Device Software – How to comply?





# Medical Device Software – Cybersecurity



- Malware and attack
- Privacy
- Natural disasters
- Technical failures
- Use error
- Political restrictions



OVHcloud data centre located in Strasbourg burned down on March 10th, 2021

## CYBERSECURITY

Hackers Have Crippled Another

M  
C **Hospital Medical Devices Used As Weapons In Cyberattacks**

Cyber Security

Add to myFT

Patients in limbo as cyber attack shuts three hospitals

Thousands of operations cancelled after NHS trust closes down computer systems

# AI ACT - Regulation EU 1689/2024



EU Artificial  
Intelligence Act


## Objective:

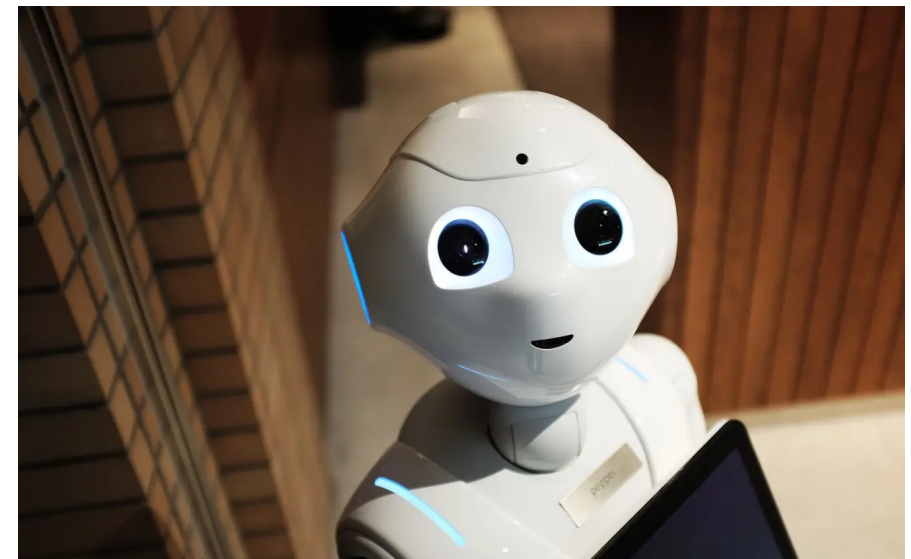
- Ensure AI in the EU is safe, transparent, and respects fundamental rights.

## Risk-Based Approach:

- Unacceptable Risk: Banned (e.g., social scoring, biometric surveillance)
- High Risk: Strict obligations (e.g., healthcare, law enforcement)
- Limited Risk: Transparency required (e.g., chatbots)
- Minimal Risk: Free use (e.g., games, spam filters)

## Key Requirements (for High-Risk AI):

- Risk management systems
- High-quality datasets
- Transparency and human oversight
- Robust cybersecurity
- Post-market monitoring
-  Mandatory Conformity assessment process



Kim Rochat



- Art. 7 Conditions for consent
- Art. 9 Processing of special categories of personal data
- Art. 25 Data protection by design and by default
- Art. 26 Joint controllers (in clinical studies)
- Art. 32 Security of processing

