Regulatory, quality and clinical affairs

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

Session 1

Kim Rochat

last update 2025-03-14

Meet the speaker

Kim Rochat – Regulatory Enthusiast

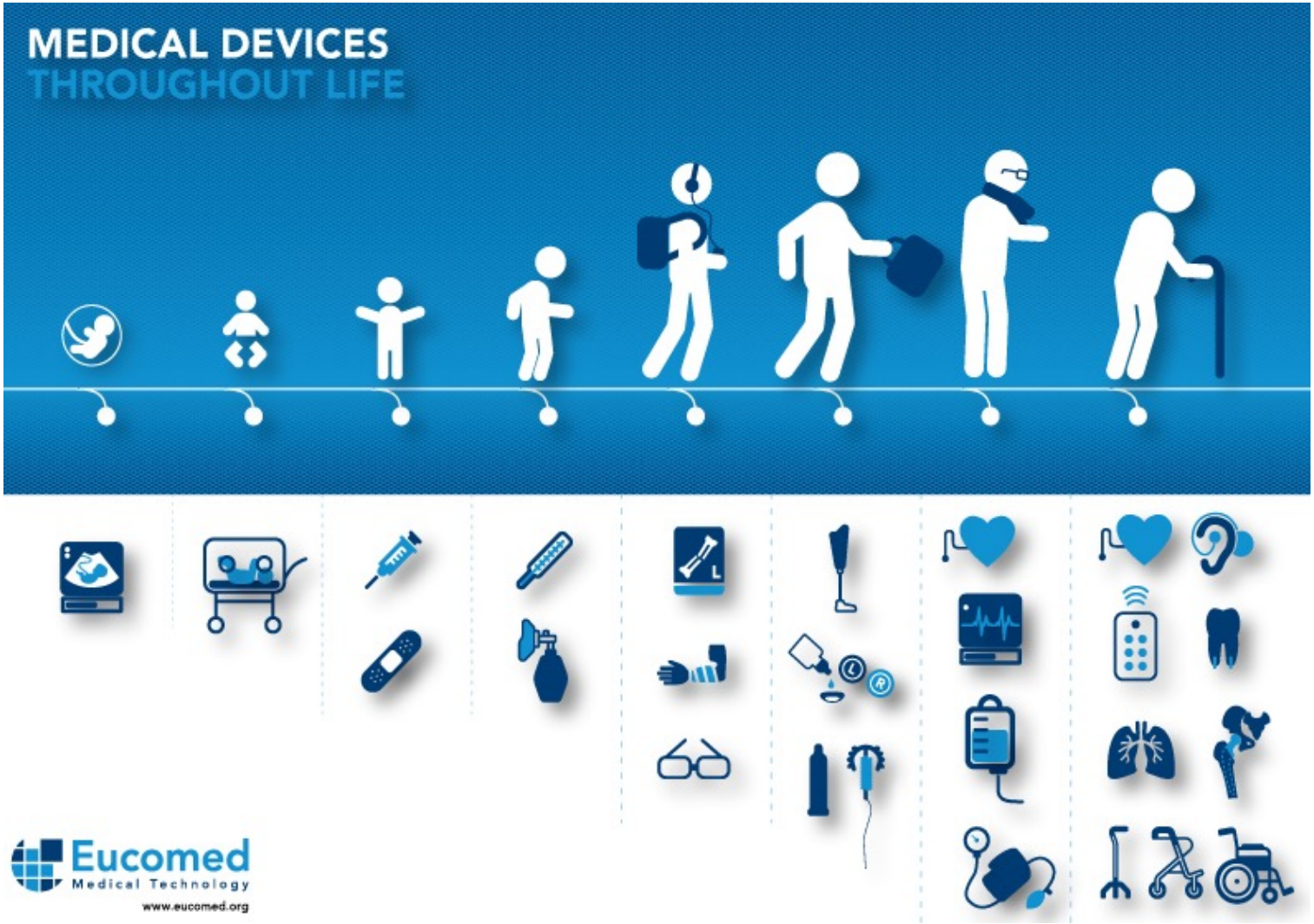
Education

- Degree in Economics
- MSc in Information System Security Management
- CAS in Medical Informatics
- CAS in Project Management
- CAS in Management of Biotech, Medtech & Pharma venture (MOT)
- Degree in Data Protection

Experience

- Co-founded Medidee Services in 2013
- Veranex acquired Medidee Services in 2022
- Served as SVP Quality and Regulatory for Veranex
- Support Manufacturers as Senior Advisor
- Coached or supervised the CE marking of 50+ medical devices and IVDs.
- Coached and / or supervised 30+ ISO 13485 QMS and ISO 27001 setup projects
- Coached the clinical investigation setup of 20+ studies

Medical devices throughout our lives



Source: Eucomed

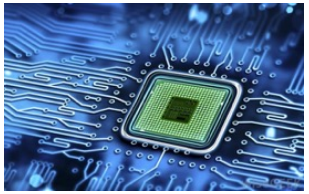
Medical Technologies – World of Diversity…

Medical Technologies – Values

Medical technologies provide value in different ways:

- They allow people to live **longer** and **better** lives, thus empowering them to contribute to society for longer.
- At the same time, medical technologies improve the **quality** of care, and the **efficiency** and **sustainability** of healthcare systems.

Medical Technologies – …and Competences



Electronics

Medicine

Mechanics

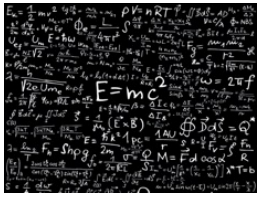
Statistic

Biology

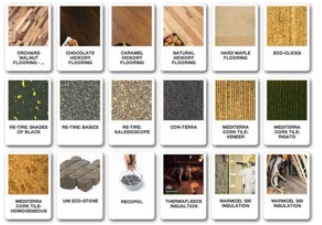
Software

Chemistry

Toxicology

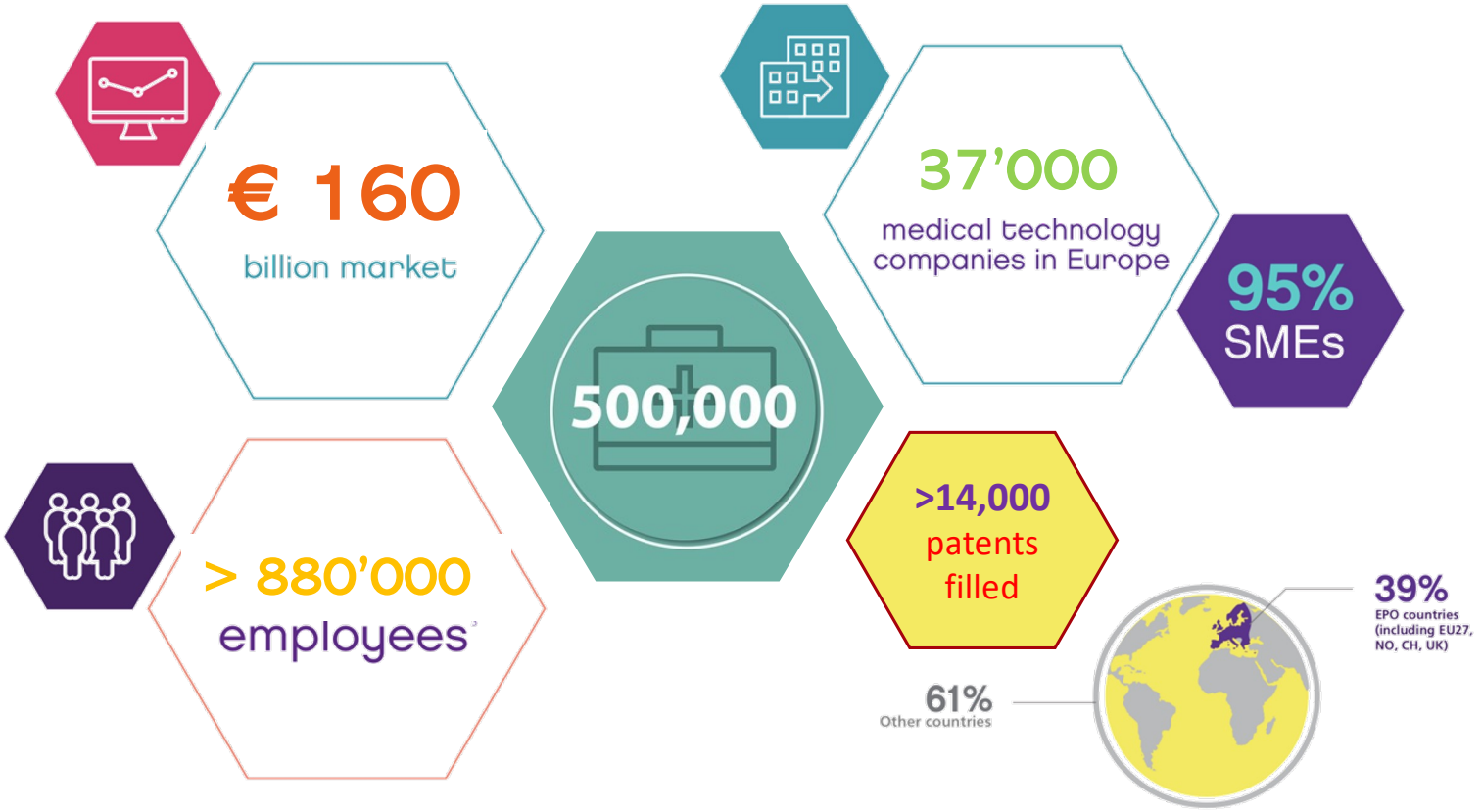


Physics



Materials

MedTech Industry – Europe

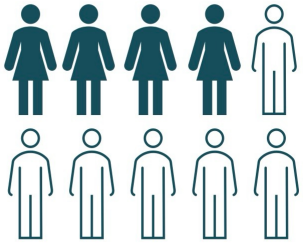


Source: MedTech Europe 2019

Kim Rochat

MedTech Industry – Switzerland

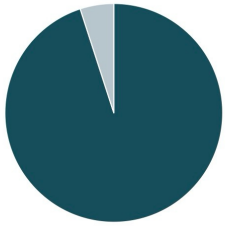
WORKFORCE



71,700

of which, 40 % women

COMPANIES



1,400

of which, 95 % SME

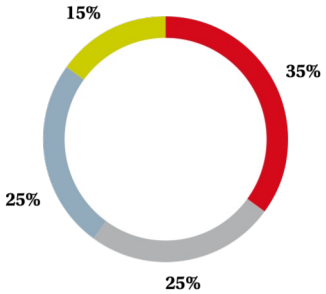
INNOVATION

12 %

revenue spent on Research & Development

Focus of Activities

Of Swiss medical technology companies



Source: SMTI, 2018

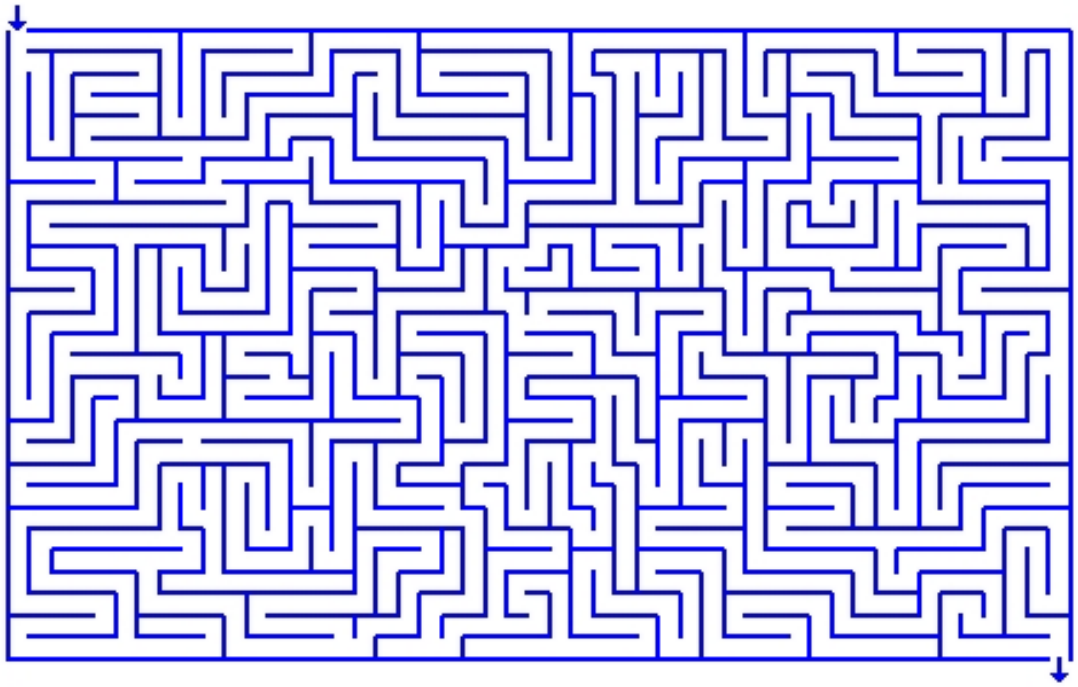
Top 10 Medtech Companies

According to number of employees, 2017

J&J Medical	Zimmer Biomet
Roche Diagnostics	Straumann
Biotronik	B. Braun
Sonova	Ypsomed
Medtronic	Dentsply Sirona

Source: Swiss Medtech 2024

MedTech Industry– Highly regulated Industry



European Regulations
Medical Device regulations
In Vitro Diagnostic Device regulation

Data Protection
HIPAA, GDPR, Data Protection directive, LPD, …

US Code of Federal Regulation
CFR 820, Part 11, etc.

Europear
Guidance
MDCG

Best practice
GCP, GLP, GM
etc.

Research
Clinical trials
Directives, LRH, ORH

Borderline
Device Manual

CE

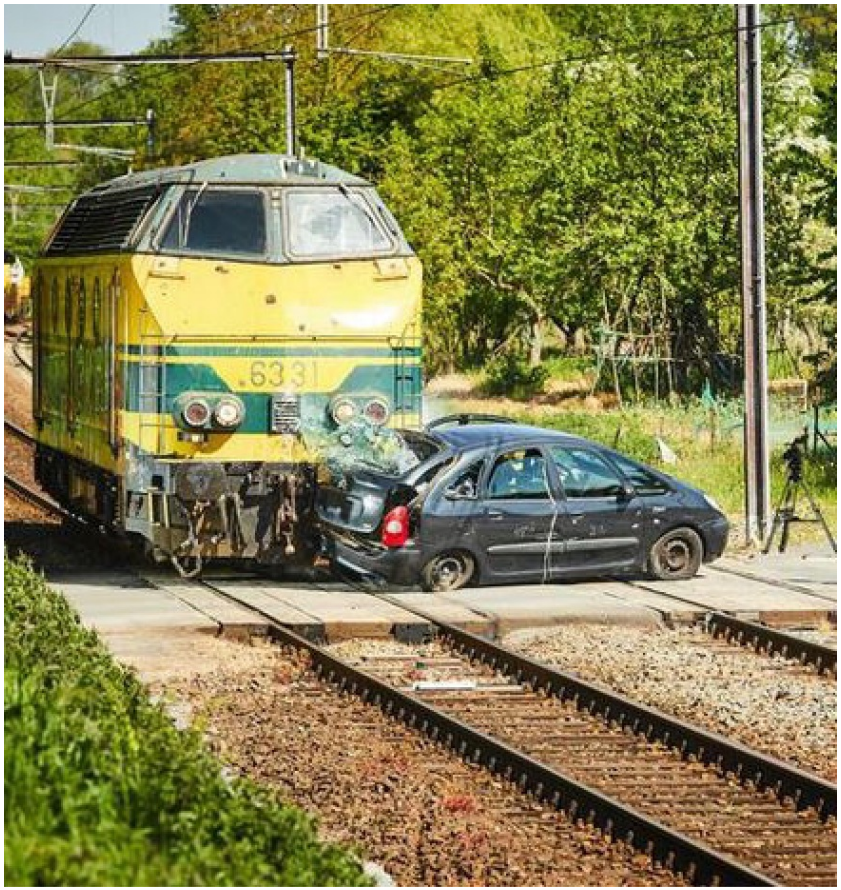
FDA
510(k)

Why regulations are essential

- They prevent tragedy by applying capitalized knowledge over time, ensuring that medical devices are continually tested, improved, and held to high safety and efficacy standards.

- They ensure the safety of patients by setting stringent standards that medical devices must meet, minimizing risks and ensuring effectiveness throughout their lifecycle.

- They define a common framework that ensures ethical business practices by establishing clear guidelines for compliance, transparency, and accountability in the development, manufacturing, and marketing of medical devices.



Regulatory, quality and clinical affairs

- **Regulatory** refers to the laws, guidelines, and standards that govern the design, manufacturing, and distribution of medical devices to protect public health while ensuring safety and performance.
- **Quality** refers to ensuring that devices placed on the market are safe, effective, reliable, and consistently meet regulatory and customer expectations. It covers the entire lifecycle of a device, from design and manufacturing to post-market surveillance
- **Clinical Affairs** refers to the processes and activities related to the clinical evaluation and clinical investigations of medical devices. It focuses on the collection and analysis of clinical data to demonstrate the safety, performance, and effectiveness of medical devices while ensuring patient safety.

Regulatory, quality and clinical affairs

- Regulatory
- Quality
- Clinical affairs

- Safety & Performance of Medical devices placed on the market
- Compliance with all laws and rules that applies in multiple countries
- Support the integration of the products within the healthcare system (i.e. reimbursement)
- Support / guide company activities to meet legal expectations

Regulatory, quality and clinical affairs

Medical Device Regulation(s)

Medical Device Development

Risk Management

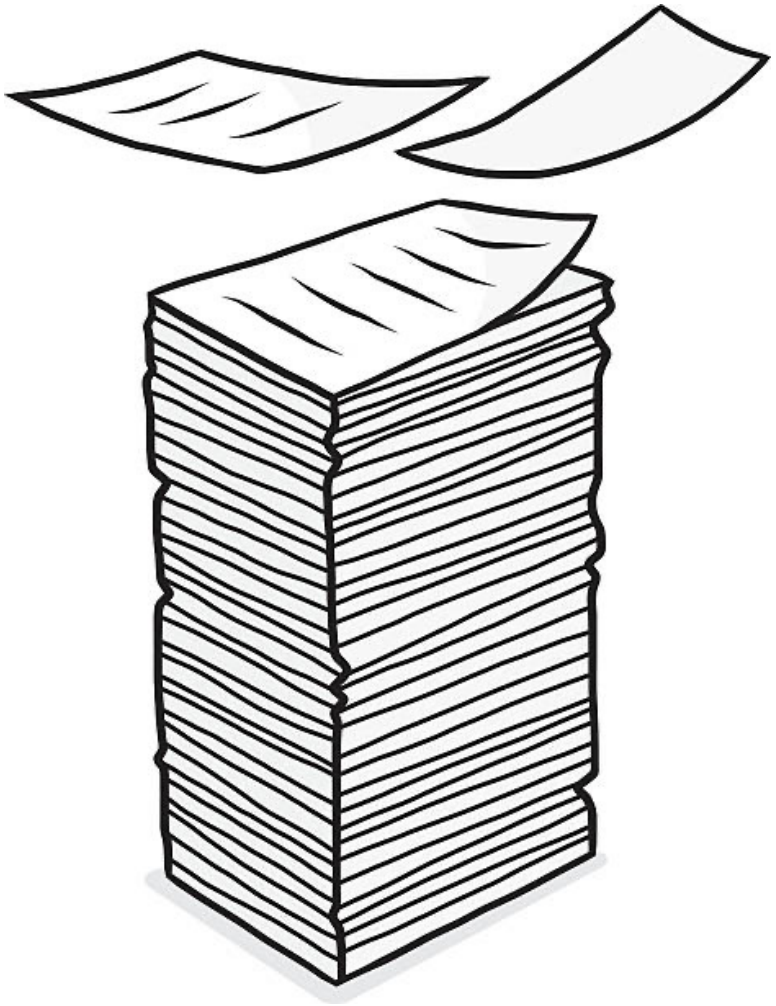
Quality Management

Clinical Activities

Digital Health

- Understand the overall implications of a project in the medical device field
- Anticipate constraints associated with the development and manufacturing of a medical device
- Plan key steps associated with the development and manufacturing of a medical device
- Identify key resources to support your activities within the medical device field

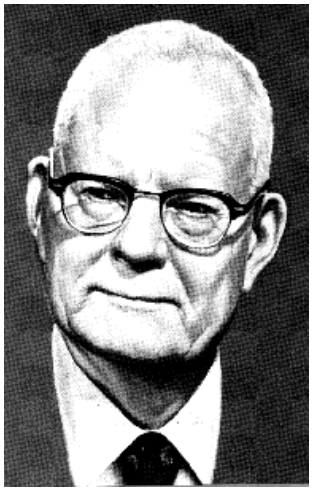
My product is a medical device—Doctor, is it serious?!"



EU Legislation

Medical Device – Evidence based medicine

William Edwards Deming
(1900 – 1993)



- Medical devices must meet stringent safety and performance standards to ensure reliability and clinical benefit.
- Devices must prioritize patient safety, minimizing risks through robust engineering practices.
- **Evidence** are required to demonstrate **safety** and **effectiveness** of device including through clinical studies.
- Development must be grounded in scientific research and clinical evidence.
- Identification, assessment, and mitigation of risks throughout the device's lifecycle shall be ensured
- **Comprehensive testing** shall be made to confirm devices meet design and performance criteria.
- Regulatory requirements must be achieved to be placed on the market.

“In God we trust, all others bring data.”

Medical Device regulation – in a nutshell

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.

Prepare a Technical File

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

Clinical evaluation

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

Conformity assessment / Notification

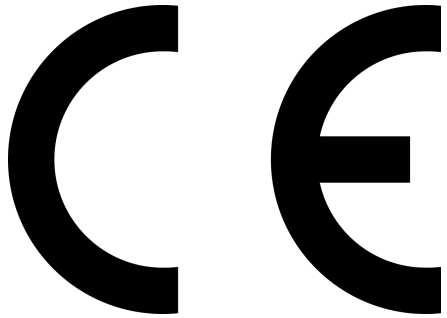
Depending on the situation, a conformity assessment with a notified body is to be done, or an authorization for a clinical investigation is to be requested or a notification shall be performed

EU Legislation – Single Market

- The **single European Market** comprises 27 Member States of the European Union, the European Economic Area – EEA (Iceland, Liechtenstein and Norway).
- **Free movement of goods** is one of the cornerstones of the single European Market
- To enable this concept of free movement, **three** conditions must be met:
  1) **Essential Requirements** for the products involved must be defined
  2) **Methods** must be established to describe how **product compliance** with the essential requirements is addressed
  3) **Mechanisms** to **supervise** and **control** the actions of all Economic Operators and others involved in the manufacturing and distribution of the products must be created

EU Legislation - CE Mark

- In the European Union (EU), various products are regulated to ensure safety, health, environmental protection, and consumer rights and are thus mandated to meet the essential requirements of relevant European directives or regulations.
- ‘CE marking’ serves as a visible indicator of product safety, quality, and compliance with EU regulations, benefiting both businesses and consumers by fostering market transparency, confidence, and access.
- CE marking applies to (list not exhaustive)
  - Electrical and electronic equipment
  - Machinery and equipment
  - Toys
  - Personal protective equipment
  - Medical devices …



CE mark is necessary to place a medical device on European market.

No CE mark = No business

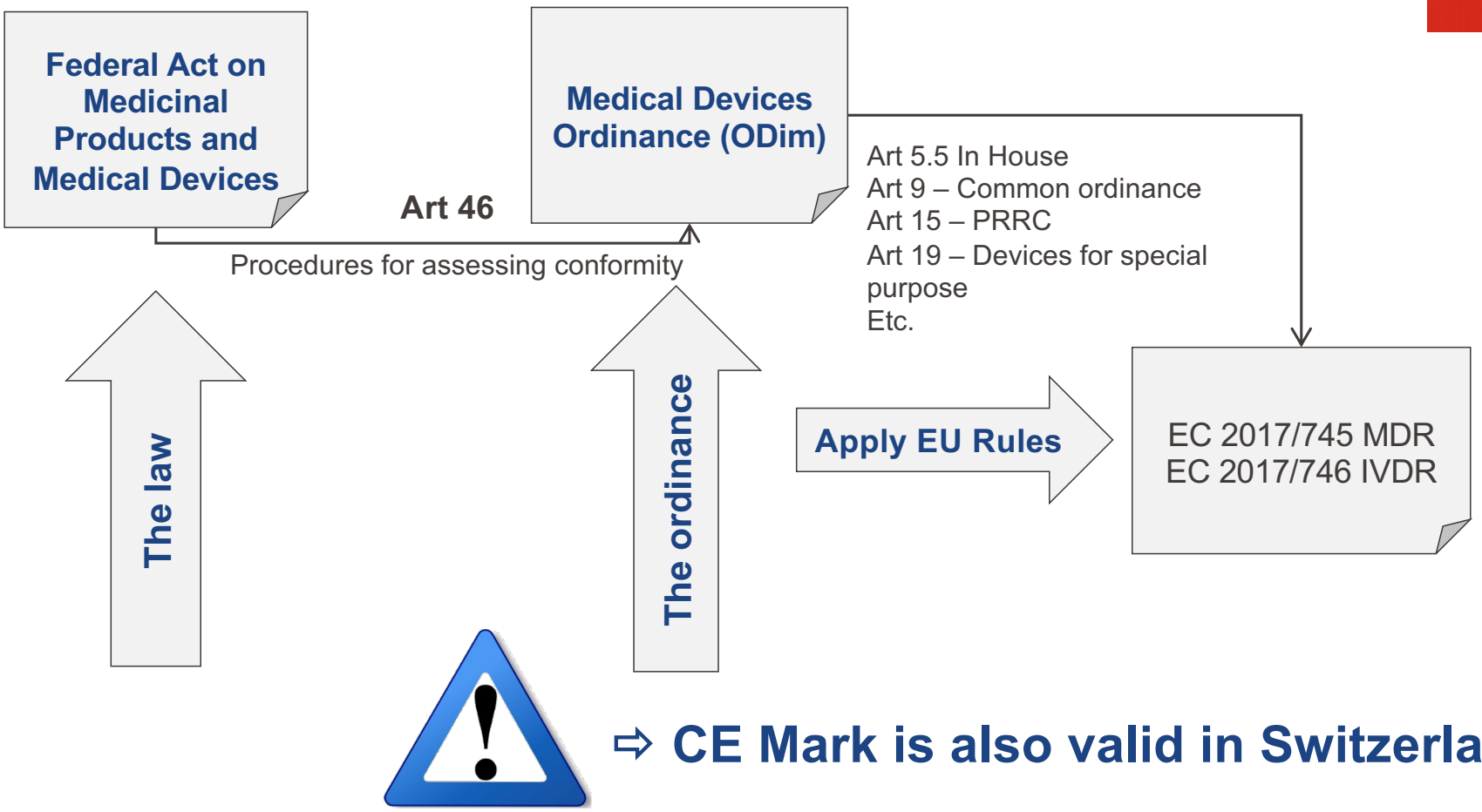
EU Legislation– Regulatory Framework

2 European Regulations
EU 2017/745 – Medical Device Regulation (MDR)
EU 2017/746 – In Vitro Diagnostic Regulation (IVDR)

National Laws
i.e . French Public Health Code, Danish Medicines Act, German Medical Devices Act, etc.

Applicable Guidance Documents (MDCG, GHTF)
Harmonized Standards (ISO, IEC, etc.)

CH Medical laws transpose EU Regulation



⇨ **CE Mark is also valid in Switzerland**

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CH Legislation – Swissxit

- On May 26th, 2021 The Swiss Federal Council stopped discussion on EU Framework Agreement
- EU decided not to recognize Switzerland anymore
- Switzerland is now a third country for EU
- Switzerland and EU are discussion a 3rd bilateral treaty that may eventually be accepted in 2027

EU Medical Device Legislation history

- **Prior 1990, only national laws were applicable**
- **1990** – The EU introduced the **Active Implantable Medical Devices Directive (AIMDD)**, the first legislation to regulate high-risk devices like pacemakers.
- **1993** – The **Medical Device Directive (MDD)** was adopted to regulate general medical devices.
- **1998** – The **In Vitro Diagnostic Medical Devices Directive (IVDD) (98/79/EC)** was introduced for diagnostic products like pregnancy tests and blood glucose monitors.
- **2007** – Update of directive to include requirement with regards to **software** and **standalone** software

EU Medical Device Legislation history
PIP Scandal

- **Poly Implant Prothèse (PIP)** were breast implants sold globaly
- **2010:** French health authorities discovered that PIP was using unauthorized silicone, which had a higher risk of rupture.
- **March 2010**: PIP implants were banned and recalled globally. To date over 15’000 patient have been explanted
- **2013:** Jean-Claude Mas, PIP’s founder, was convicted of fraud and sentenced to four years in prison.
- **2023:** The French Supreme Court ruled that **TÜV Rheinland**, the company responsible for certifying PIP implants, was **liable for damages**.
- PIP **illegally used industrial-grade silicone** instead of medical-grade materials in its breast implants, affecting **400,000 to 500,000 women worldwide**.

EU Medical Device Legislation history
PIP Scandal consequences

- European Commission set the Dalli Plan which was a set of measures proposed in response to the PIP breast implant scandal.
- The goal was to strengthen the regulation of medical devices in the European Union and prevent similar incidents in the future.
- Immediate actions:
  - Stronger Market Surveillance
  - Better traceability of medical devices
  - Tighter Controls on Notified Bodies
  - Introduction of a joint assessment system to improve communication between national health regulators.
  - Initiation of the Medical Device Regulation reform

EU Medical Device Regulatory Reform Impacts

- One single text applicable over all member states – no national interpretations
- Catch up with technological innovation
- Enhance control over Notified Bodies
- Eliminate grey zones in current regulation
- Improve transparency and information exchange between stakeholders
- Technical improvements in the texts to clarify requirements

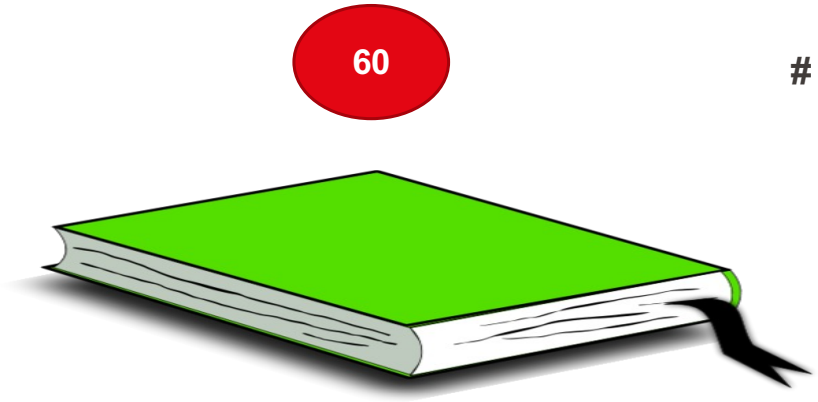
⇒ All for promoting the objective of safety

Practical impacts:

- All medical devices on the market must be re-certified
- All Notified body must be re- designated
- Requirements and controls skyrocketed.

Medical Device – European Regulation

In 2021 the Medical Device Regulation (MDR) entered into force, same for the In Vitro Diagnostic Device Regulation (IVDR) in 2022.

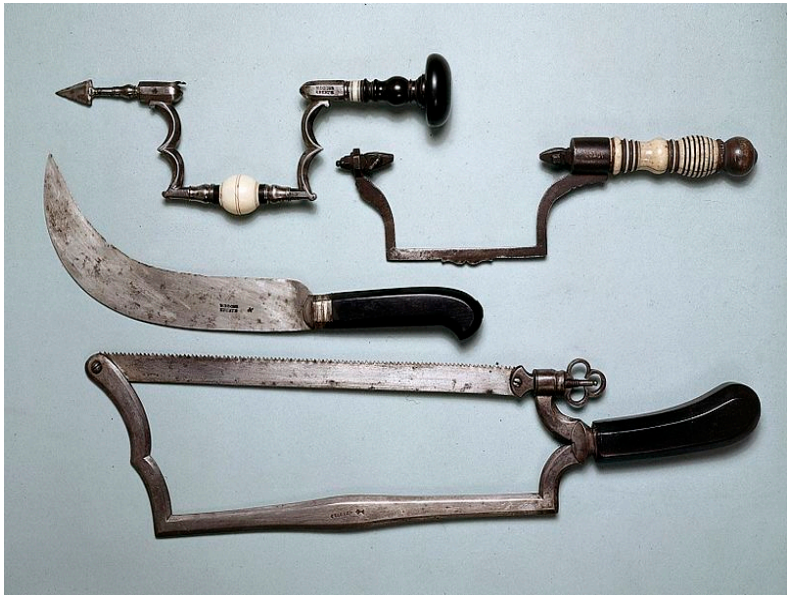


Consolidated Medical Device Directive
93/42/EC

# of Pages

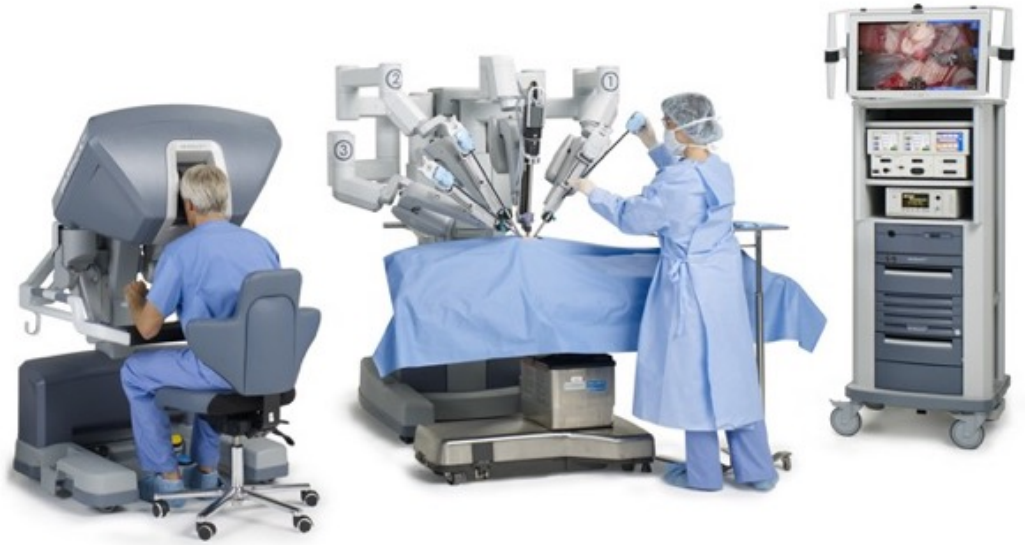
Consolidated Medical Device Regulation
2017/745

What is a medical device?



Yesterday…

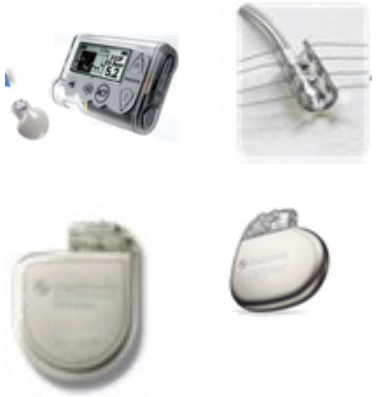
Today…



Medical Technologies – Main Categories

Medical Device

AIMD



IVD

Software

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Medical Device – what is the definition?

Option 1 - A medical device refers to any equipment, implant, or product that healthcare professionals use to support patient care. This includes devices for diagnosis, monitoring, surgical procedures, and rehabilitation.

Option 2 - A medical device is a specialized tool rigorously regulated to ensure their safety and effectiveness, and they are vital in improving the overall quality of healthcare.

Option 3 - A medical device is like a magician's wand for doctors. They wave it around, say some medical jargon, and, poof, you feel better!

Medical Device – Definition (MDR)

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) '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.

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.

Medical Device – Definition (Simplified)

- **medical device**' means **any instrument, reagent, material, software**… for diagnosis and treatment of disease, injury, disability

- which does **NOT** achieve its **principal intended** action by pharmacological, immunological or metabolic means, …,

- but which may be assisted in its function by such means.

Medical Device – Definition

Kim Rochat

These **are** medical devices:

- Stethoscopes
- Incision drapes
- Syringe for infusion pumps
- Wound dressing
- Stents
- Urinary catheters
- Surgical gloves
- Cardiovascular catheter
- Breast implants
- Hip replacements systems
- Hearing heads
- Physiotherapy equipment
- Incubators for babies
- Thermometers
- Pacemakers, defibrillators
- Drug eluting stents

Medical Device – Definition

These are **NOT** medical devices:

- Baby nappies
- Toothbrushes
- Winkle treatments
- Toilet equipment for disabled
- Mask for protection of users
- Eye protective visors
- Self rescue apparatus
- Sunglasses
- « Wellness » software
- Piercing

However, it **depends**… on their **Intended Purpose**

Medical Device – Definition

Sunglasses => *Corrective glasses*

Mask for protection => *Surgical masks*

Intended Purpose – Definition

"**intended purpose**" means the use for which a device is intended according to the …

- label
- instructions for use; and
- promotional or sales materials / statements
- online publication / web site

and

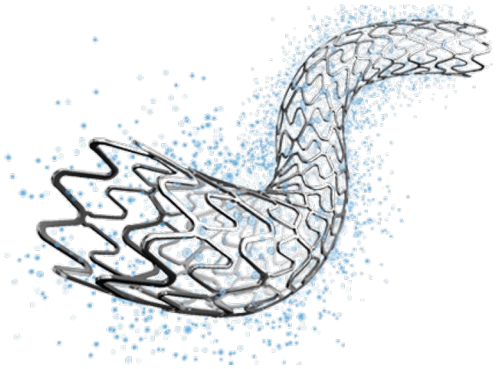
- as specified by the manufacturer in the **clinical evaluation**
- based on the **claims made** for the device

Medical Device – Intended Action

Principle intended action:

- *Physical means* => ***Device Regulation***
- *Pharmacological, immunological, or metabolic means* => ***Drug Regulation***

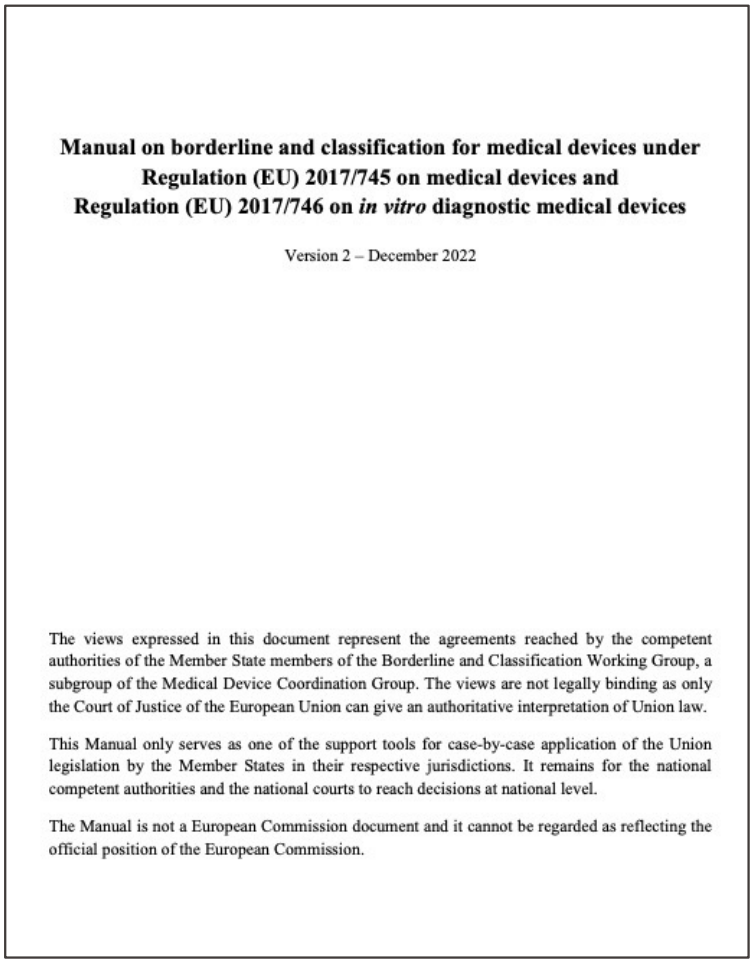
Medical Device ?



Medical Device – Borderline

- Borderline cases are considered to be those cases where it is **not clear from the outset** whether a given product is a medical device, an in vitro diagnostic medical device, an active implantable medical device or not.

- There may be cases where 'claims' of a medical nature are made for certain products, where those **claims cannot be substantiated by technical, clinical and scientific data**.



Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

Version 2 – December 2022

The views expressed in this document represent the agreements reached by the competent authorities of the Member State members of the Borderline and Classification Working Group, a subgroup of the Medical Device Coordination Group. The views are not legally binding as only the Court of Justice of the European Union can give an authoritative interpretation of Union law.

This Manual only serves as one of the support tools for case-by-case application of the Union legislation by the Member States in their respective jurisdictions. It remains for the national competent authorities and the national courts to reach decisions at national level.

The Manual is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission.

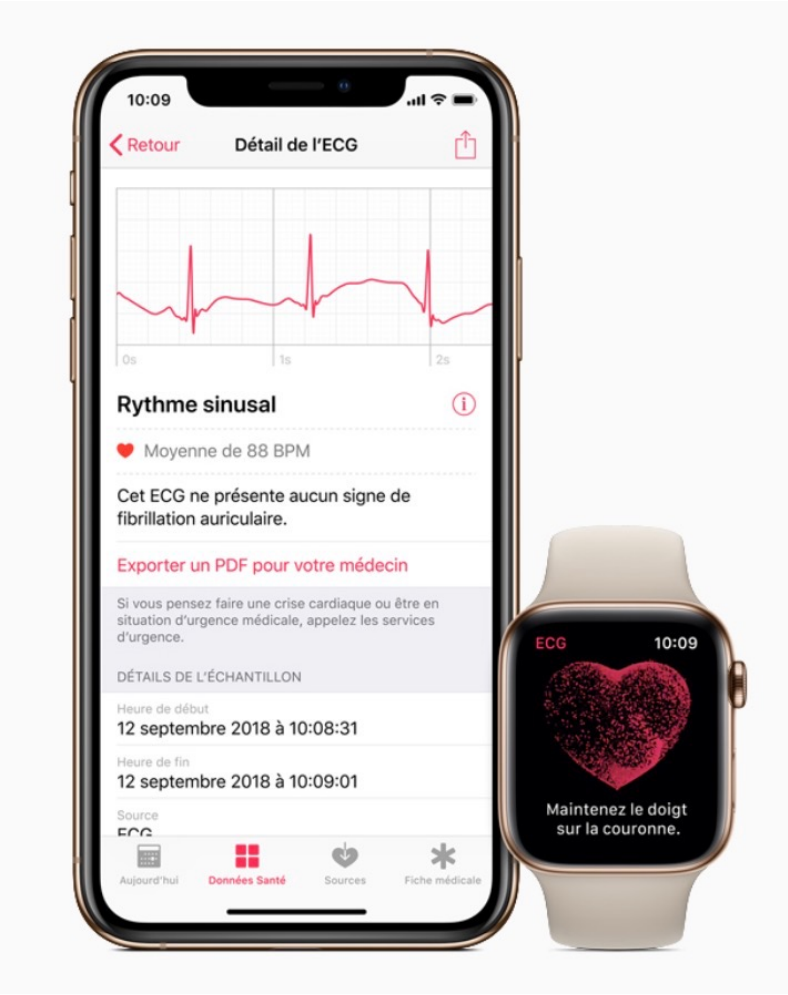
https://health.ec.europa.eu/system/files/2022-12/md_borderline_manual_12-2022_en.pdf

Medical Device without an intended medical purpose

Annex XVI provide a list of device which are regulated as medical devices although they do not have a medical purpose.

- Contact lenses or other items intended to be introduced into or onto the eye
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain

Medical Device or not a Medical Device?



iWatch
General Consumer Product

Electrocardiogram (ECG) Sensor
Medical Device

- **Function:** Records an ECG similar to a single-lead electrocardiogram and can detect atrial fibrillation (AFib).
- **Intended purpose** : intended to monitor and detect a medical condition (AFib).

Sleep apnea detection tool
Medical Device

- **Function:** detects small movements at the wrist associated with interruptions to normal respiratory patterns during sleep.
- **Intended purpose** : intended to detect signs of moderate to severe sleep apnea

Q&A