

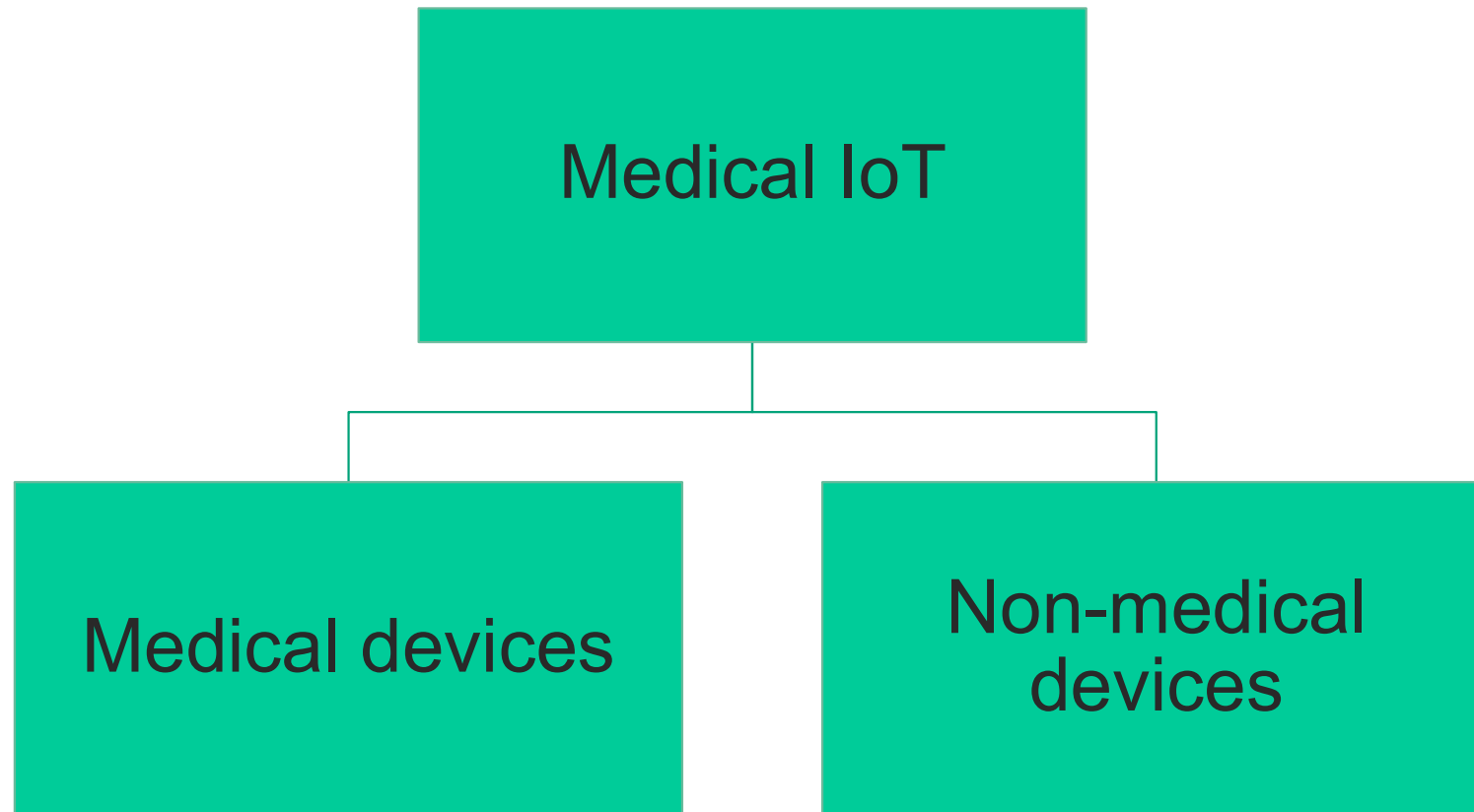
**Warsaw University
of Technology**

Cybersecurity Requirements in Post Market Surveillance of Medical IoT

Jarosław Greser, PhD

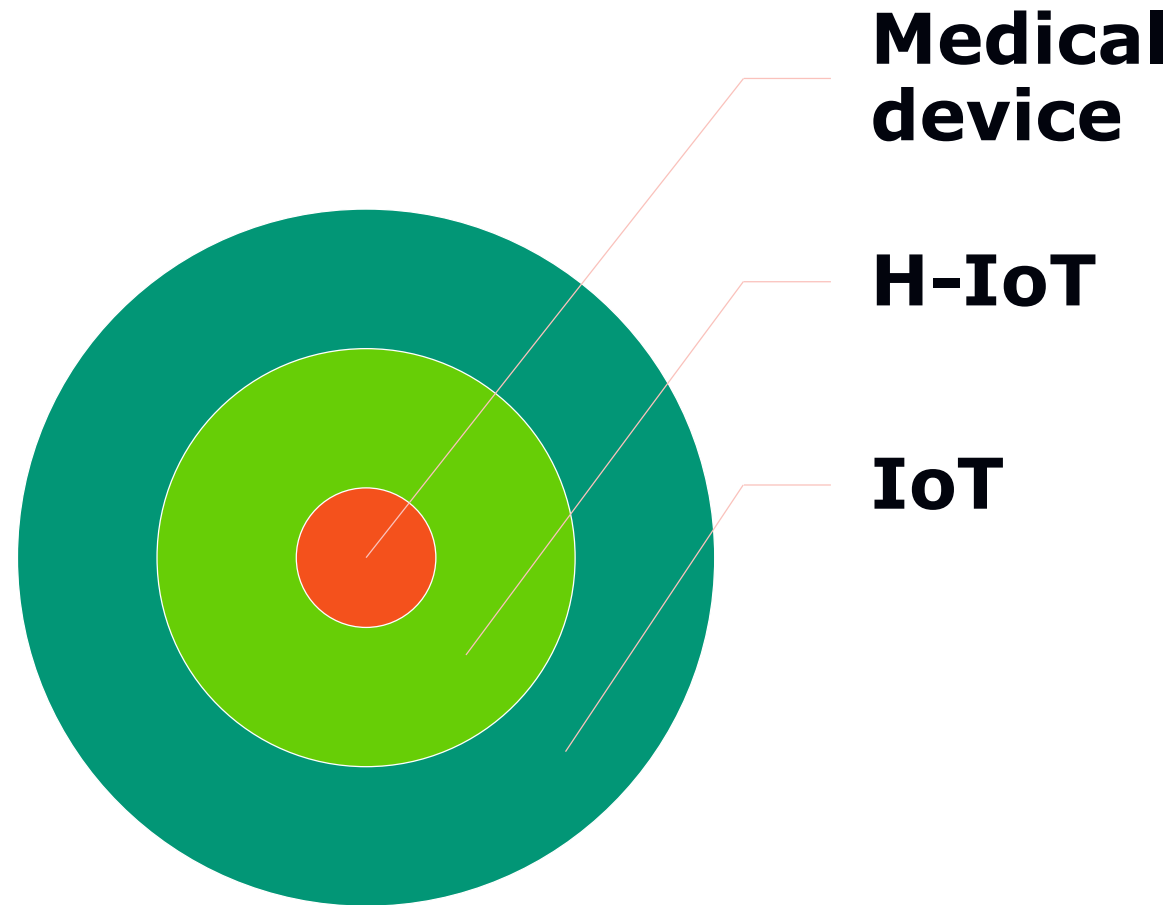
Medical IoT definition (M-IoT)

2

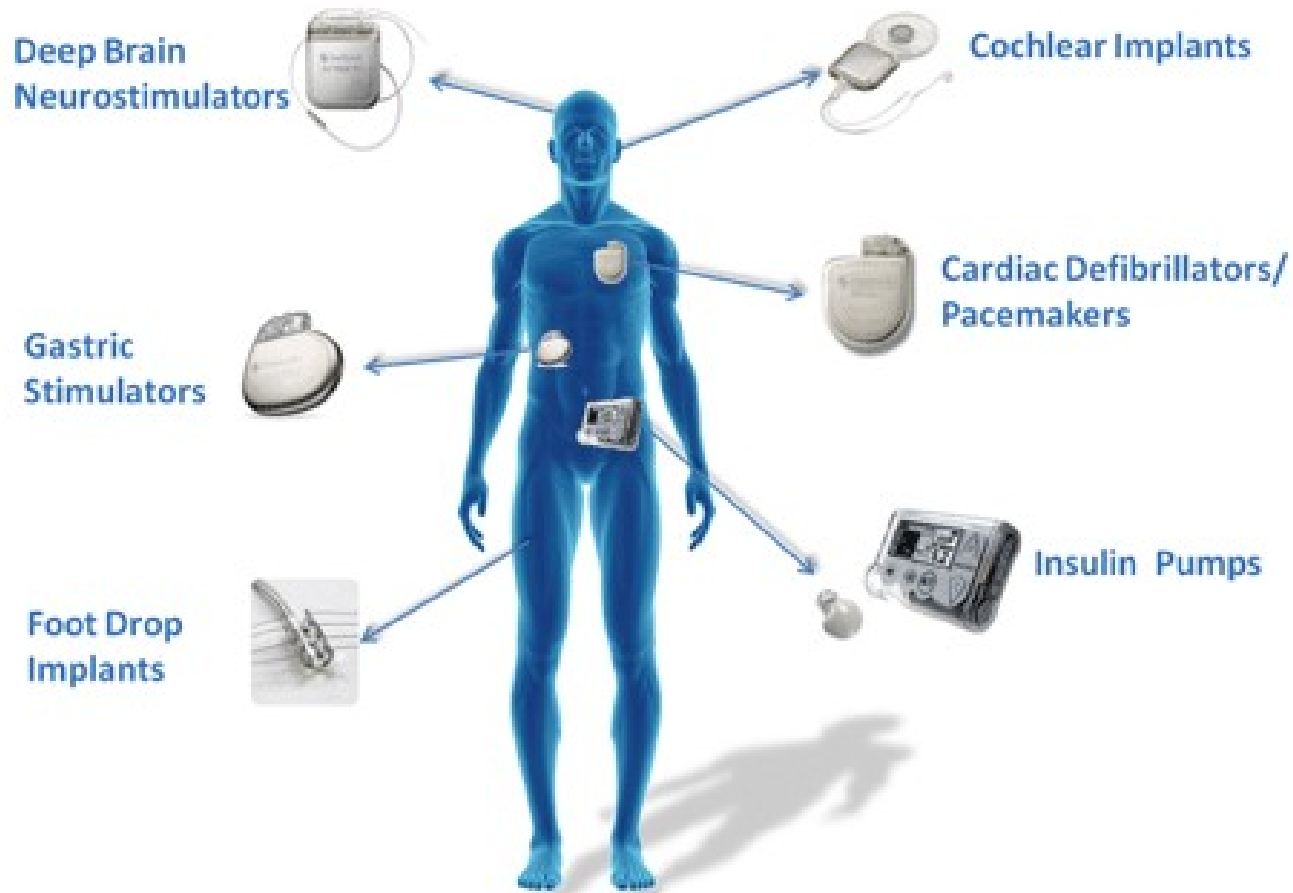


Medical IoT definition (M-IoT)

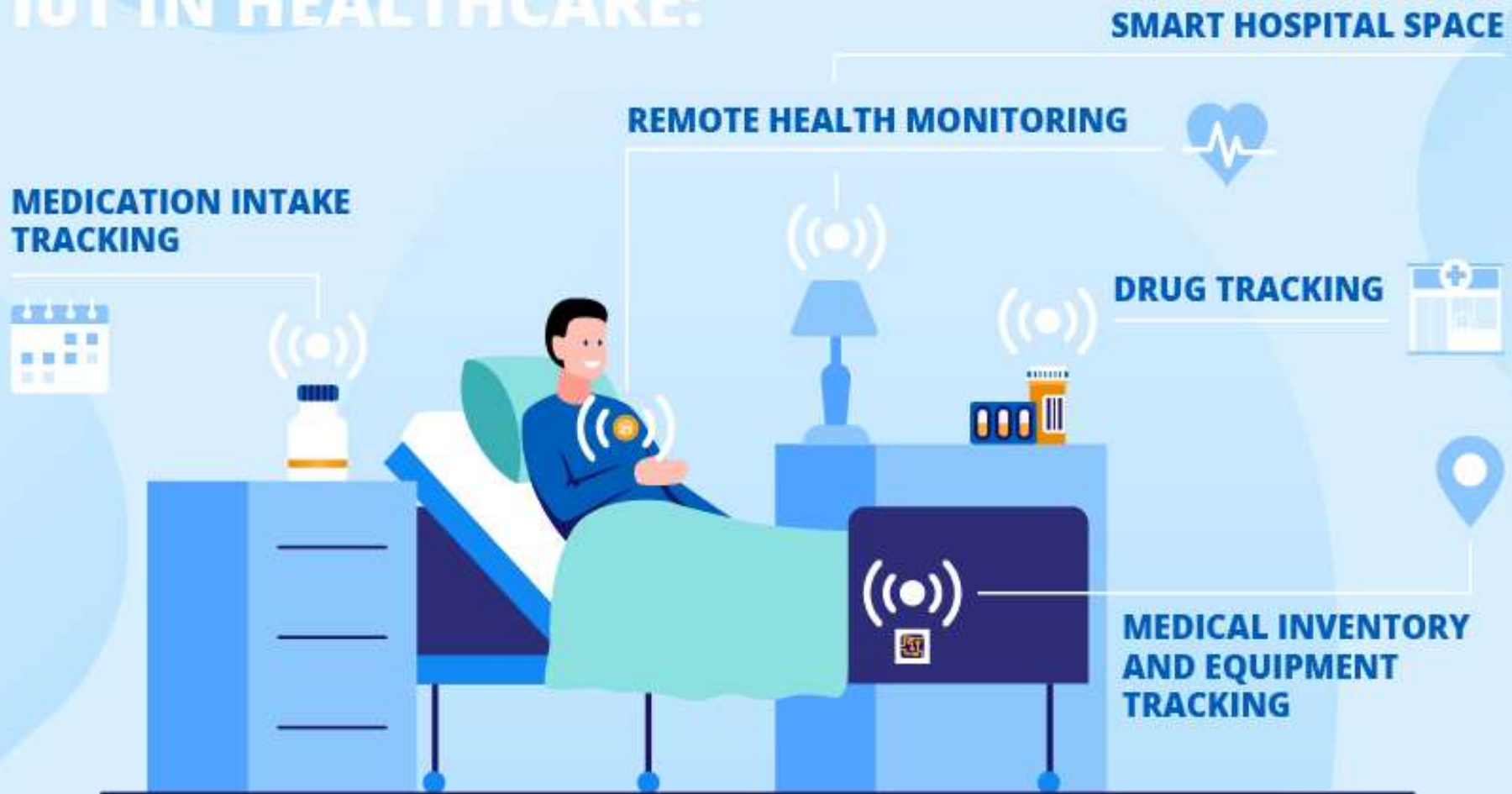
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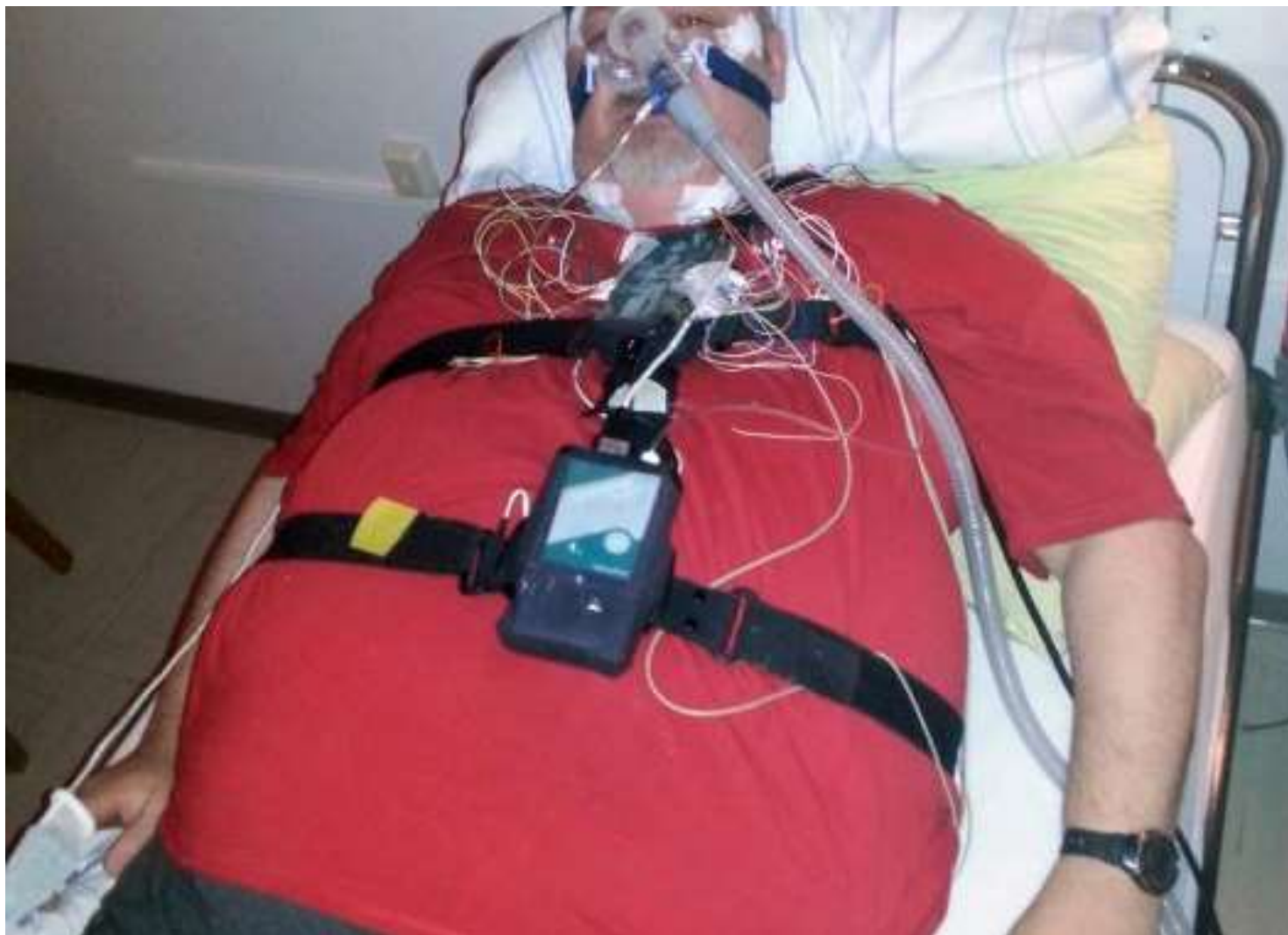


WIRELESS IMPLANTABLE MEDICAL DEVICES



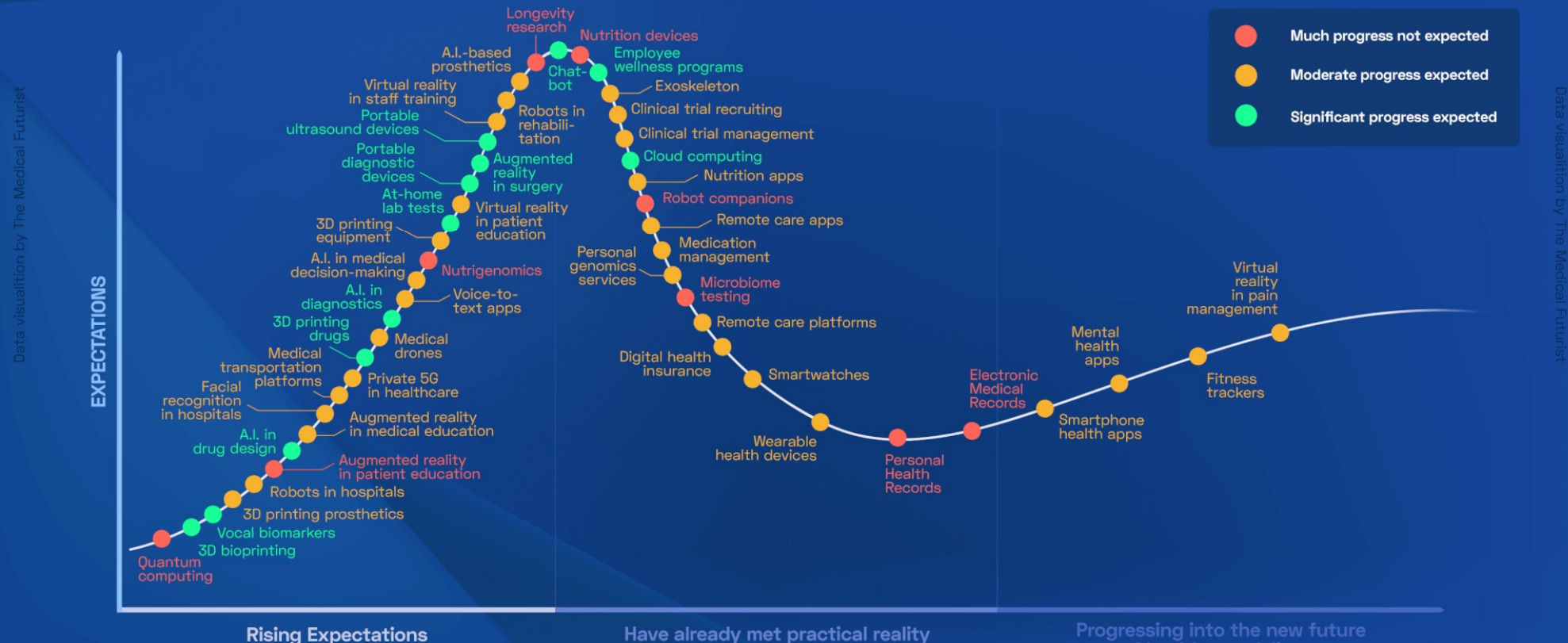
IoT IN HEALTHCARE:





Future of M-IoT

Hype Cycle Of The Top 50 Emerging Digital Health Trends



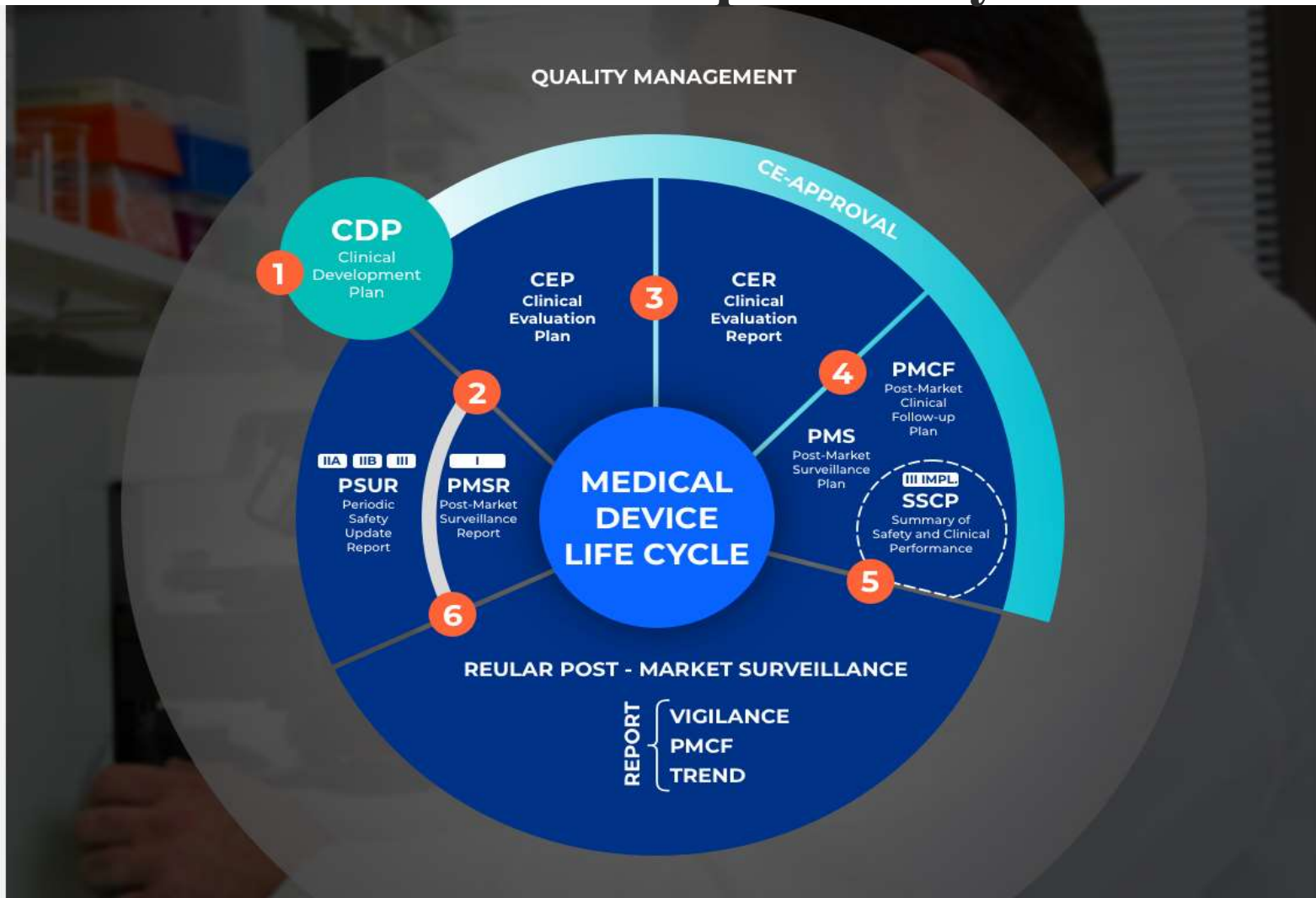
https://cdn.medicalfuturist.com/wp-content/uploads/2021/10/2023_hype_cycle_infographic_small.png

Typical cybersecurity issues of IoT

8

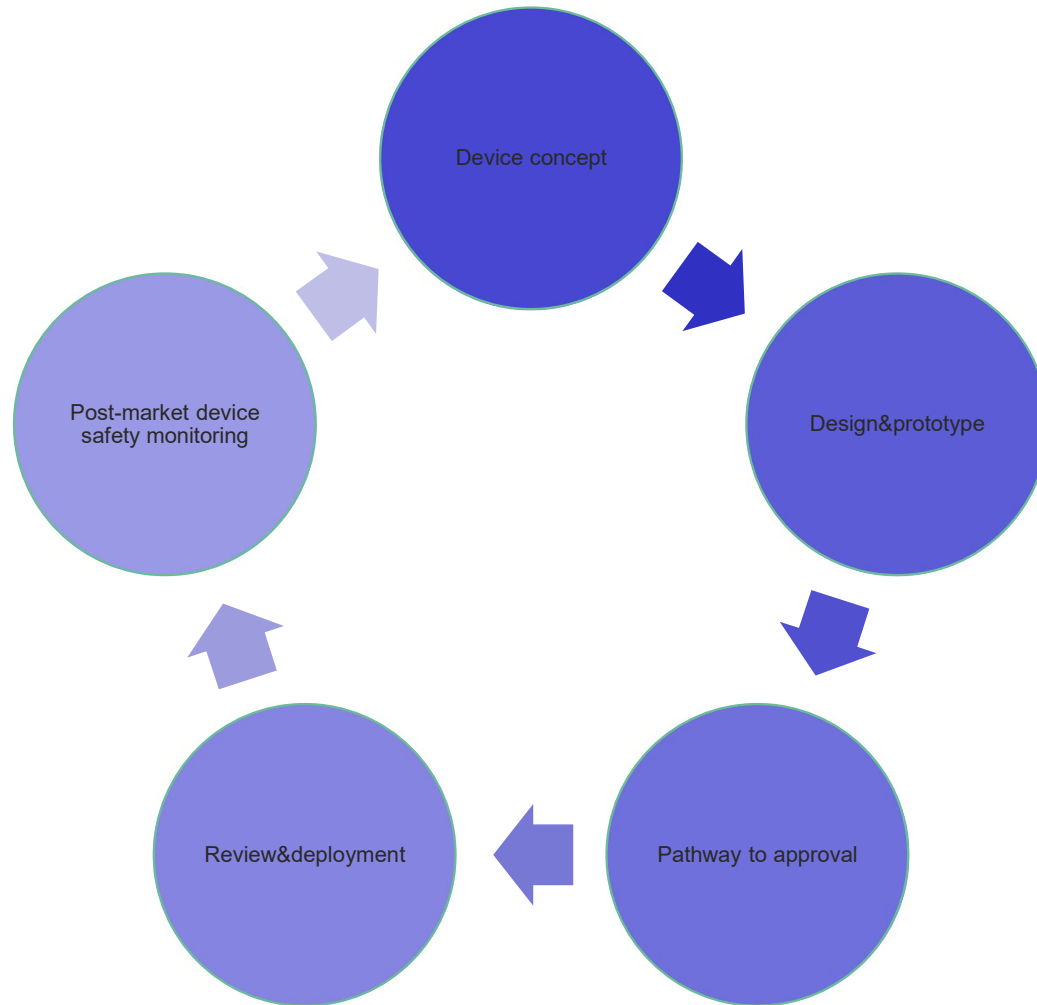
1. Design and prototyping methods
2. Technical requirements
3. Orphant devices

MDR Product Development Cycle

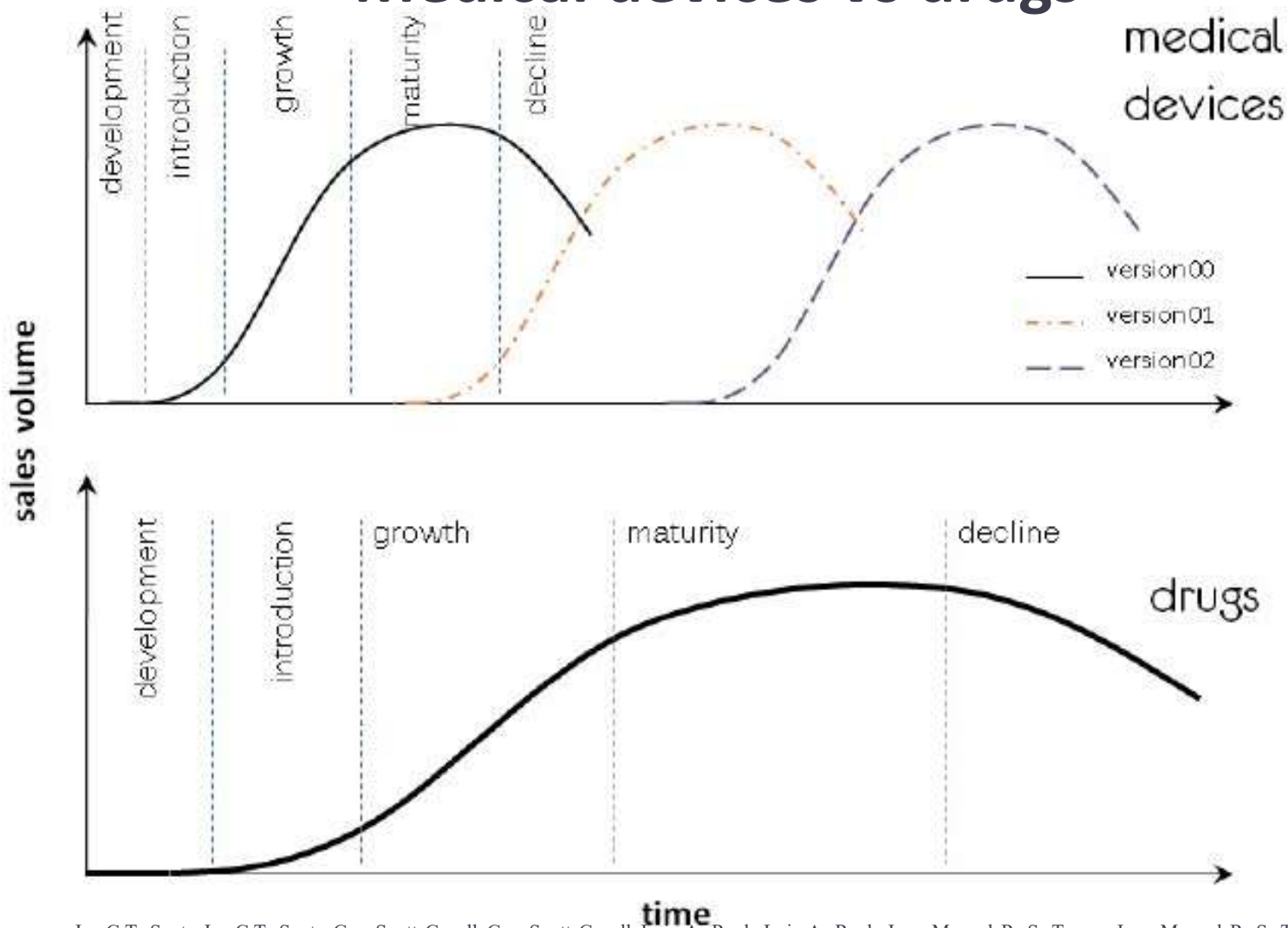


FDA Product Development Cycle

10



Medical devices vs drugs



Types of surveillance activities in MDR

12

Manufacturers	Competent authorities of a Member State
1. Post-market Surveillance 2. Vigilance	1. Market Surveillance

Types of surveillance activities in MDR

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Post-market Surveillance

1. post-market surveillance plan
2. periodic safety update report
3. analysis reporting of serious incidents
4. safety corrective actions

Vigilance

1. trend reporting
2. analysis of vigilance

Cybersecurity of medical devices in MDR

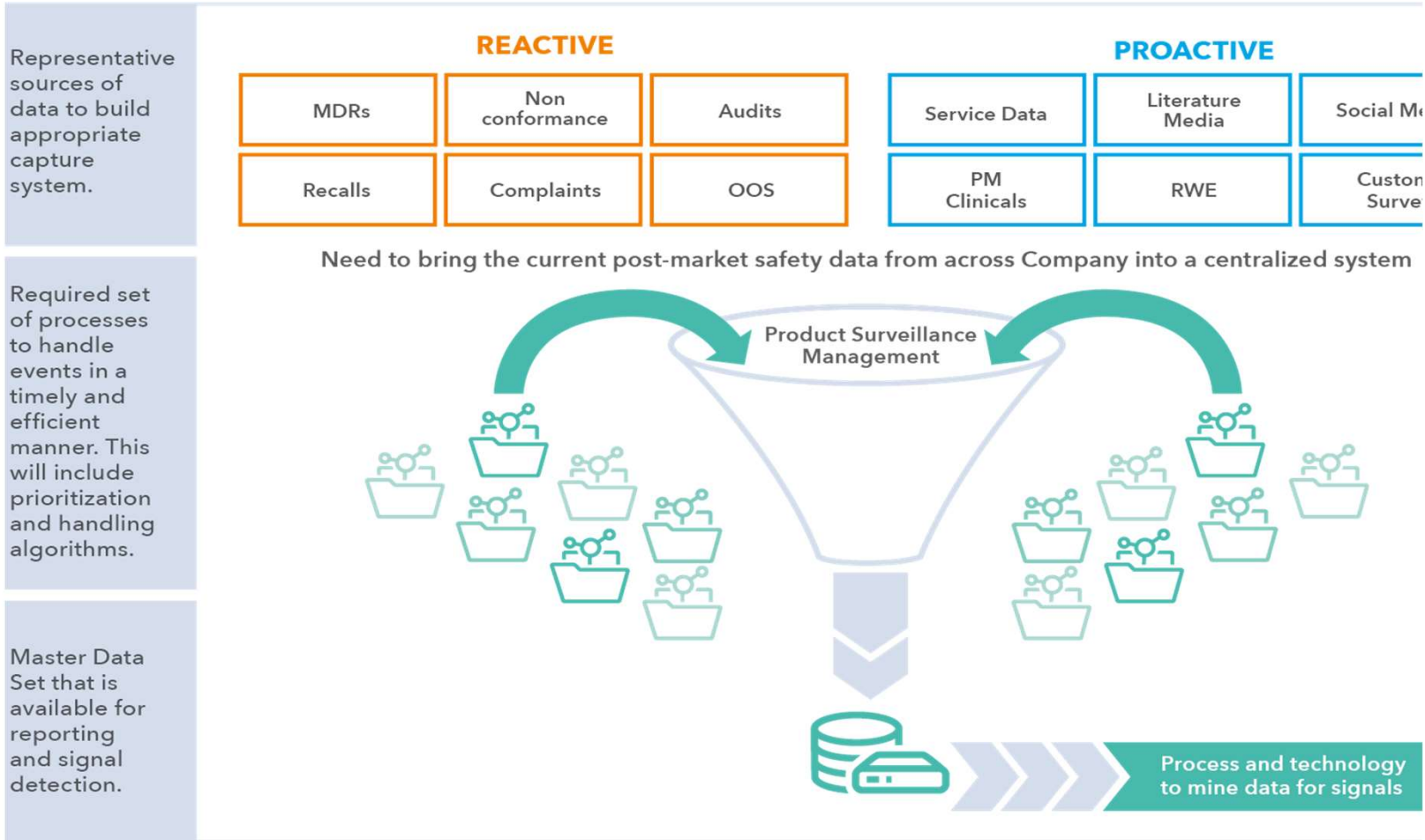
14

1. Lack of direct cybersecurity regulations
2. Any medical device placed on the market must meet the general safety and performance requirements set out in Annex I which applies to it, taking into account its intended purpose
3. The **IT security** is addressed explicitly in Annex I, Articles 17.2, 17.4, 18.8 and inexplicitly in section 1 of Medical Devices Regulations Annex I

Cybersecurity of medical devices in MDR

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1. Guidance on Cybersecurity for Medical Devices (December 2019)
2. Issued by Medical Device Coordination Group under art. 105(c)



Cybersecurity of medical devices in other legal acts 17

1. **GDPR**, in particular Articles 5(1)(f) and 32
2. **Cybersecurity Act** - the European Cybersecurity Certification Framework
3. **AI Act** - article 15 According to recital 30, this Regulation will only apply where the AI system is a safety component of the product and undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation.

Cybersecurity of non-medical devices

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1. Commission Delegated Regulation 2022/30
2. Proposal for Cyber Resilience Act
3. Sectoral regulations
4. Consumer regulations

Thank you for your attention!