

The regulatory environment for the cybersecurity of the user of the IoMT in the European Union and the United States

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IoMT

Implantable device

Clinical-grade fixed medical devices

Stationary „in-home” medical devices

Wearable medical devices

IoMT – regulatory environment

Provisions that are strictly consumer nature

Device safety regulation

Cybersecurity regulation

Provisions on the Protection of personal data

Legislation that deals with IoMT – EU and USA

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EU – Medical Device Regulation

USA – Medical Device Amendments of 1976

Legislation that deals with IoMT – EU and USA

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The regulatory approach is similar therefore the level of user protection is also similar

*What about the product liability of
IoMT manufacturers in the context
of the cyber security of IoMT users
who will be using this device, which
are consumer in nature?*

Product liability law

- **EU – Directive on liability for defective product**
USA- the Third Restatement of Torst



Thank you