



Inovação que transforma. Tecnologia que cuida.
Innovation that transforms. Technology that cares.



Desafios da Cibersegurança em Dispositivos Médicos

Painel ABIMED |  Solutions

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Agenda

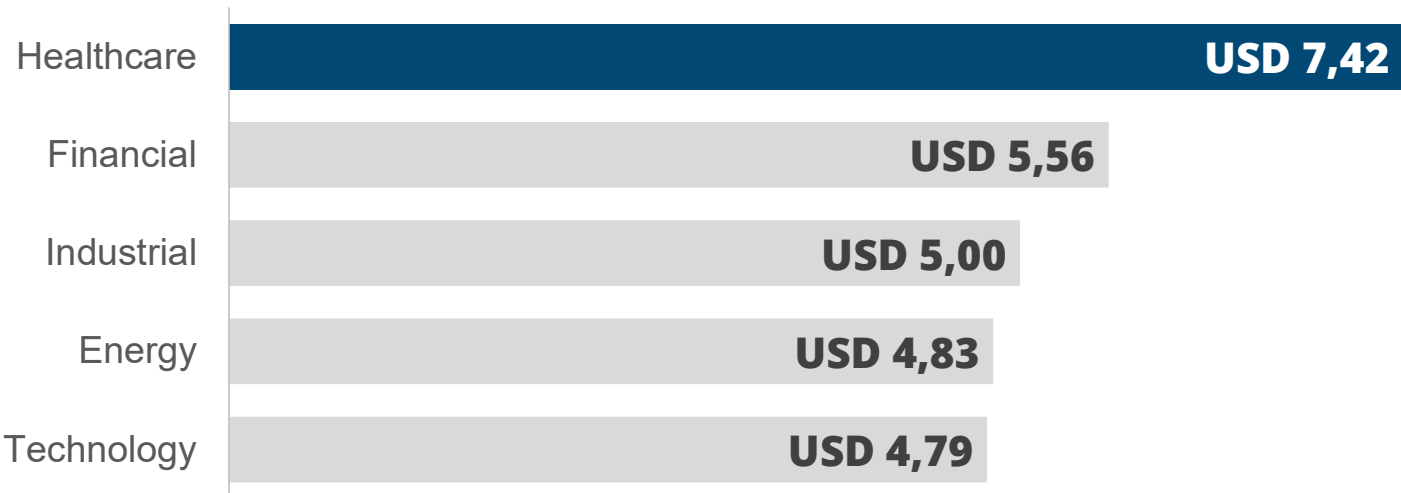
- Healthcare and cybercrime
- Global medical regulatory landscape
- Cybersecurity Global References
- Industry challenges & opportunities



Why healthcare attracts cybercriminals



Healthcare combines **valuable data, operational urgency, complex infrastructure** and **low tolerance for downtime**



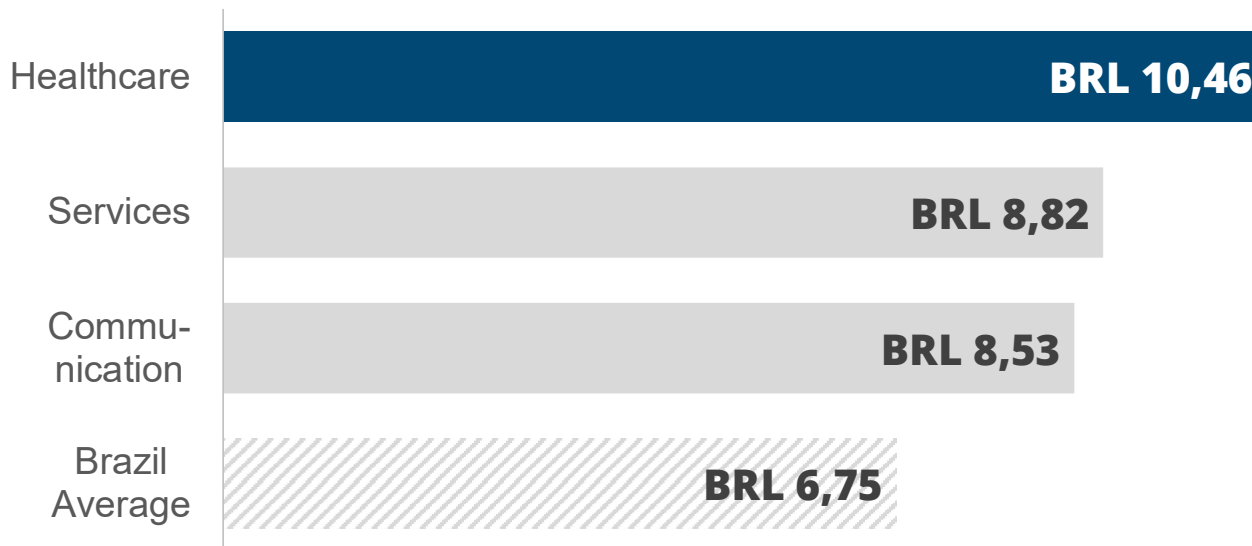
Average cost of data breach by sector, 2025 (in millions)



Cyber Risk in Brazil Healthcare



Average cost of data breach by sector, 2024 (in millions)



Brazil healthcare attack pressure

3,167

Weekly attack attempts per healthcare organization in Brazil

~37%

above the global healthcare average of 2,309

~55%

higher breach cost than Brazil's all-industry average



The attacker's business model in Healthcare

Commercial motives can create clinical consequences



Data monetization

Patient PII, insurance data, clinical data and identity data.



Operational extortion

Care delivery depends on system availability.



Complex attack surface

IT, IoMT, cloud, suppliers, remote access and legacy systems.

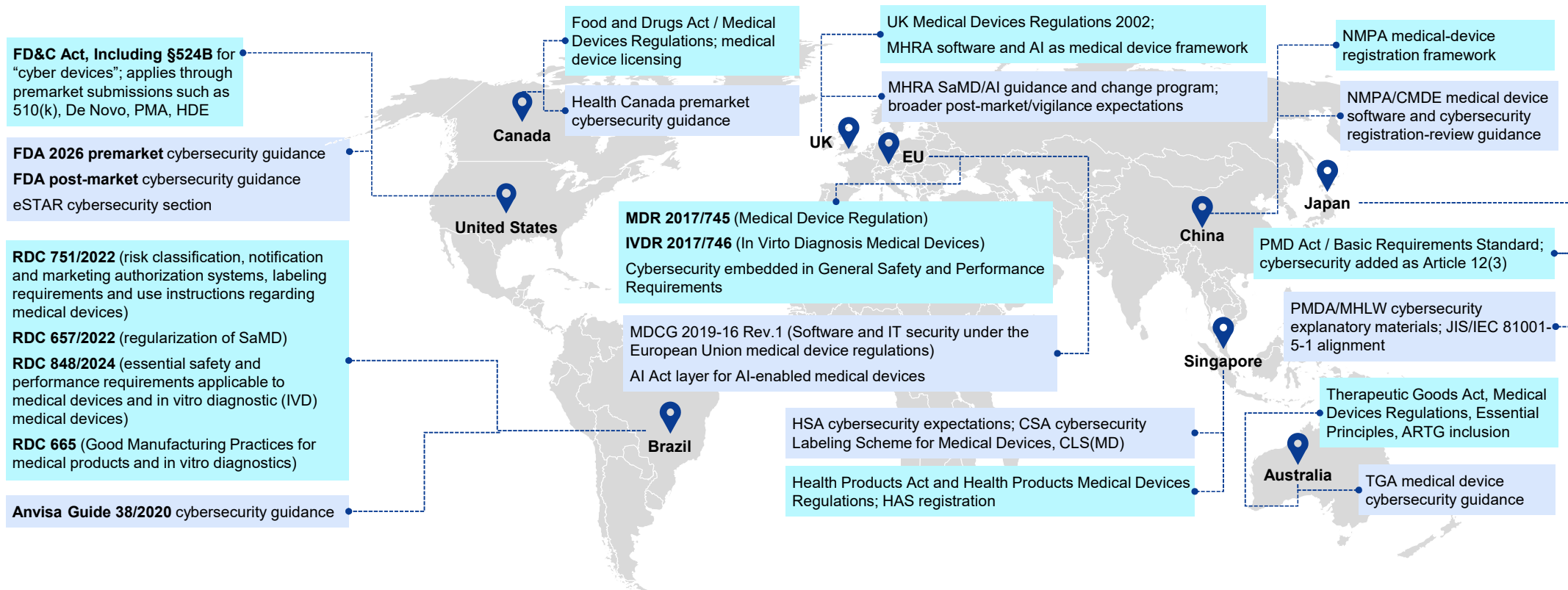


High pressure to restore

Delays can affect care, reputation and revenue.

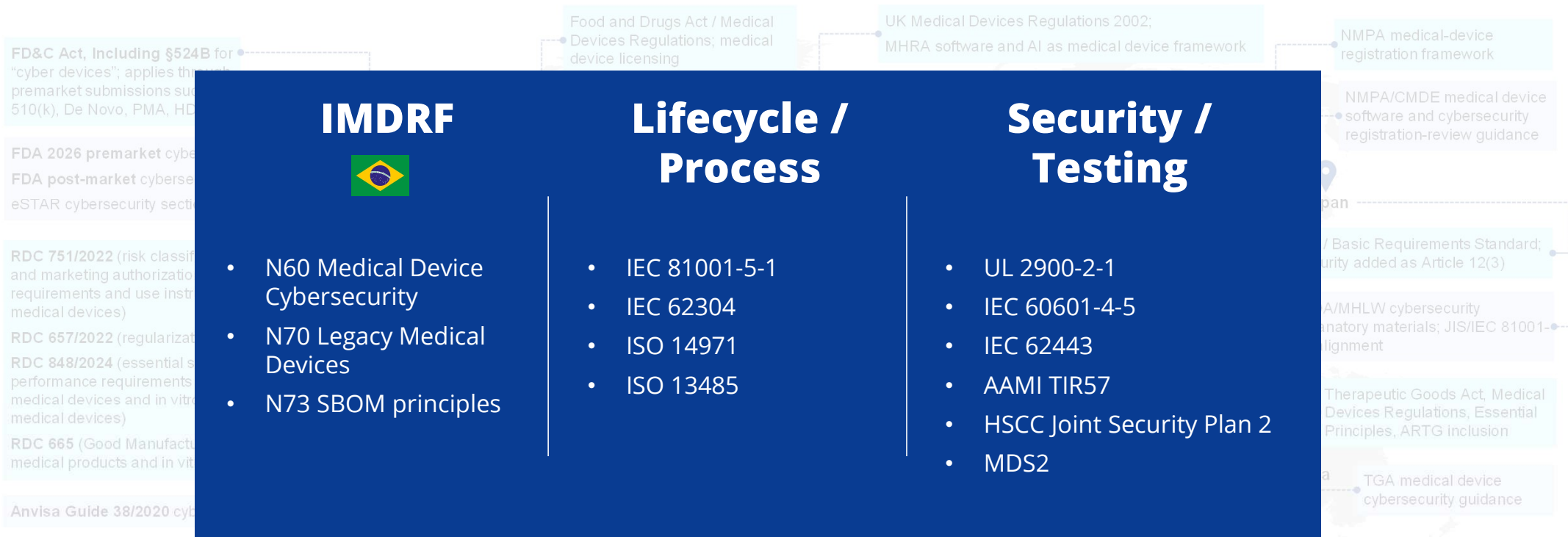
Cybercriminals do not need to attack the patient directly to create patient risk

Medical regulations, guidelines and compliance



Important Note: Non-exhaustive

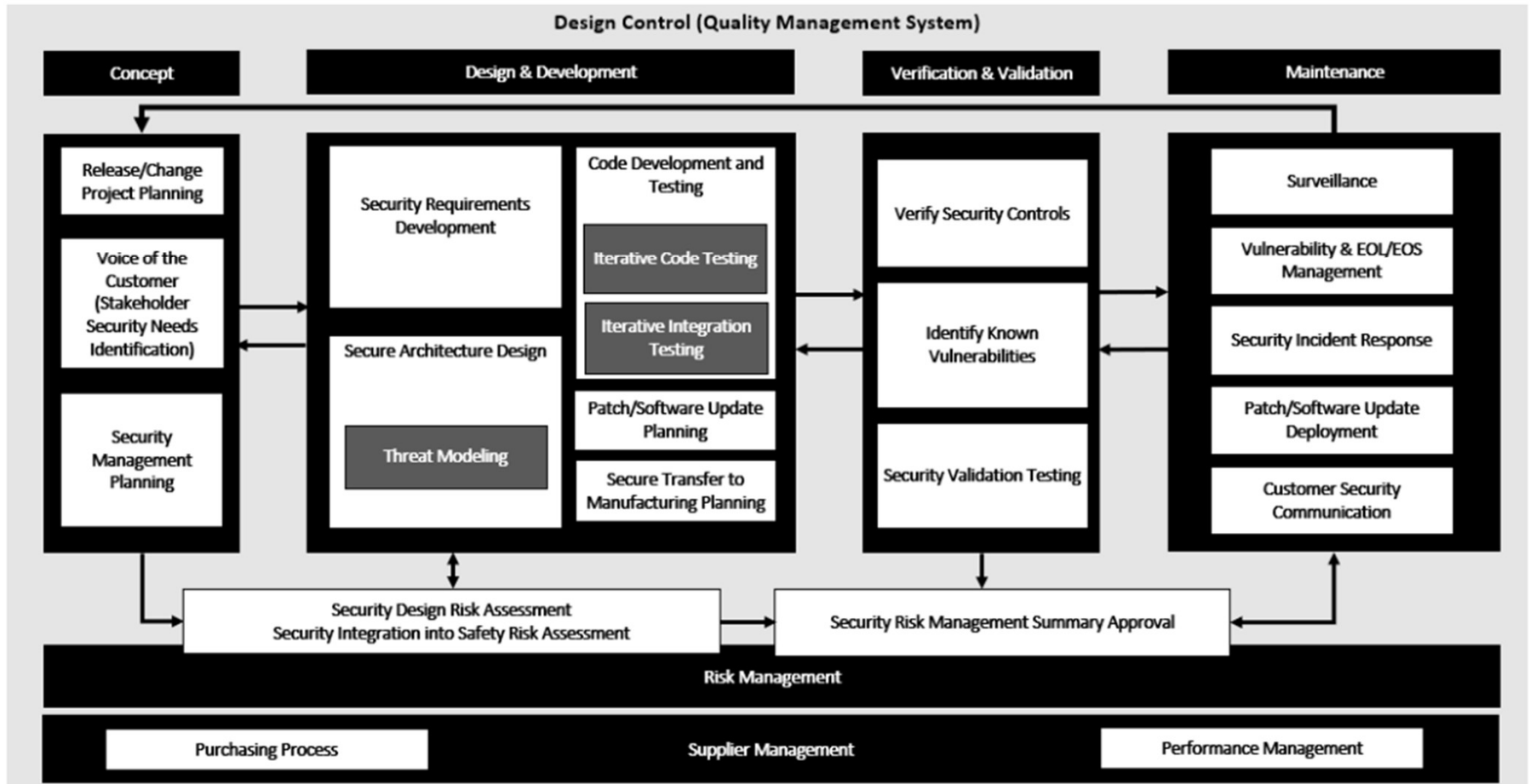
Global Harmonization & Standards



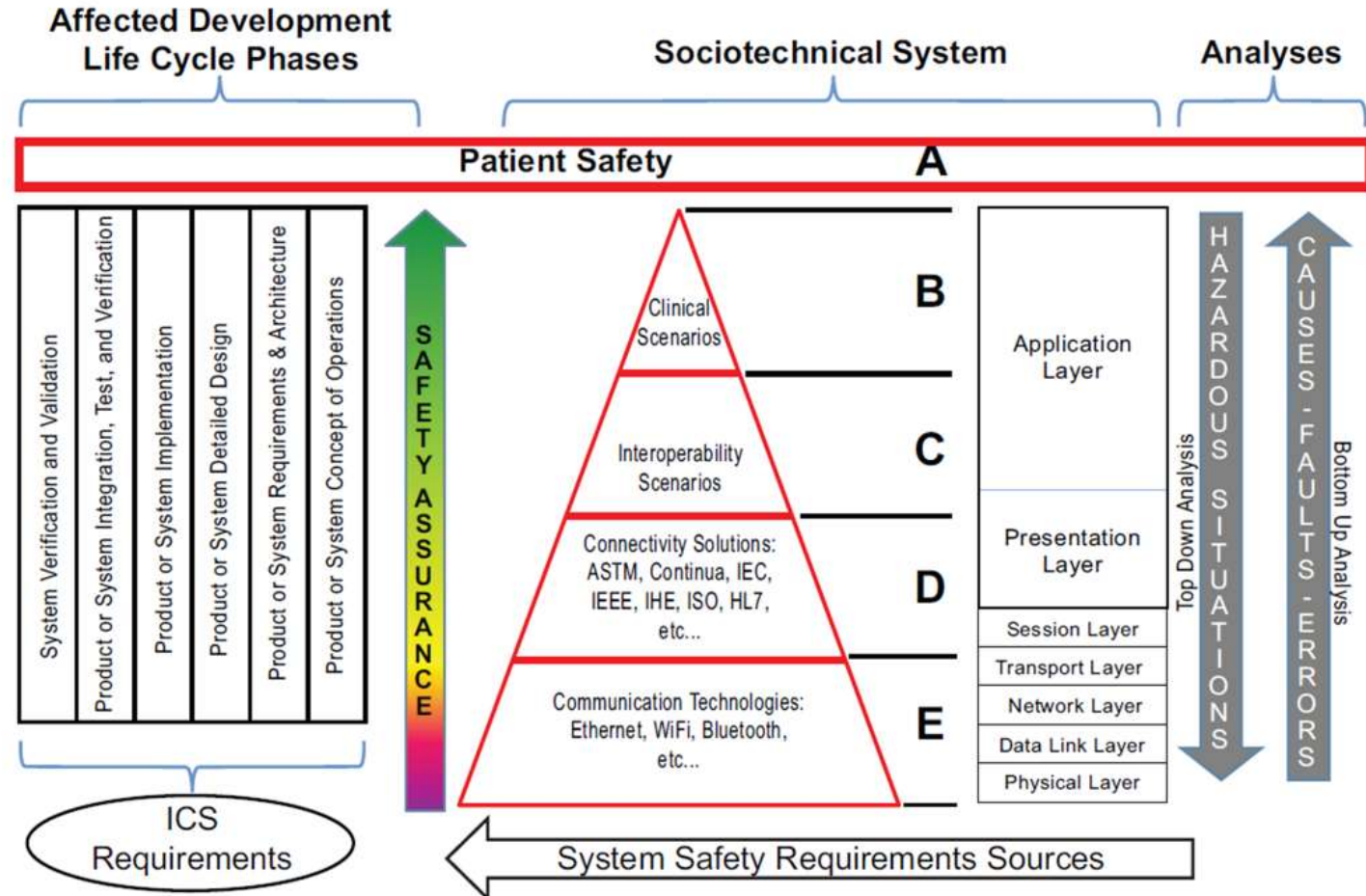
HSCC

Joint Security Plan 2 (JSP2)

Total Product Lifecycle Security Activities



Industry Challenges



su3437

Source: AAMI UL 2800-1 3rd Edition 2026

Building on Brazil's established foundation to strengthen cybersecurity

Opportunity to Leverage existing ANVISA requirements and align **selectively** with global references

1 Structured Collaboration

ANVISA, ABIMED, manufacturers, hospitals, TIC, ICT, academia and security experts **build on existing Brazilian requirements** to align on a shared, risk-based language and practical implementation priorities.

2 ANVISA-led Harmonization Map

Map Brazil's current regulatory framework (e.g., RDC 657/751) against selected global references (e.g., JSP2, UL 2900-2-1) to identify where alignment can **strengthen outcomes without creating unnecessary burden**

3 Brazil-fit, Risk-based Roadmap

Define **proportionate cybersecurity controls and evidence expectations** based on device criticality, ecosystem maturity, and shared responsibilities - supporting phased adoption that reflects Brazil's security risk profile

Decision Lens

Proportionality • Risk-based prioritization • Phased adoption • Feasibility for Brazil's ecosystem

Possible Outputs

Tiered evidence expectations • Implementation guidance • Future-ready requirements • Procurement/security criteria



30 ANOS

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ABIMED
TECNOLOGIA. SAÚDE. VIDA.

Obrigada!

Thank You!