Extending SOUP to ML Models When Designing Certified Medical Systems

Vlad Știrbu, CompliancePal/University of Helsinki, Finland
Tuomas Granlund, Solita, Finland
Jere Helén, University of Helsinki, Finland
Tommi Mikkonen, University of Helsinki, Finland

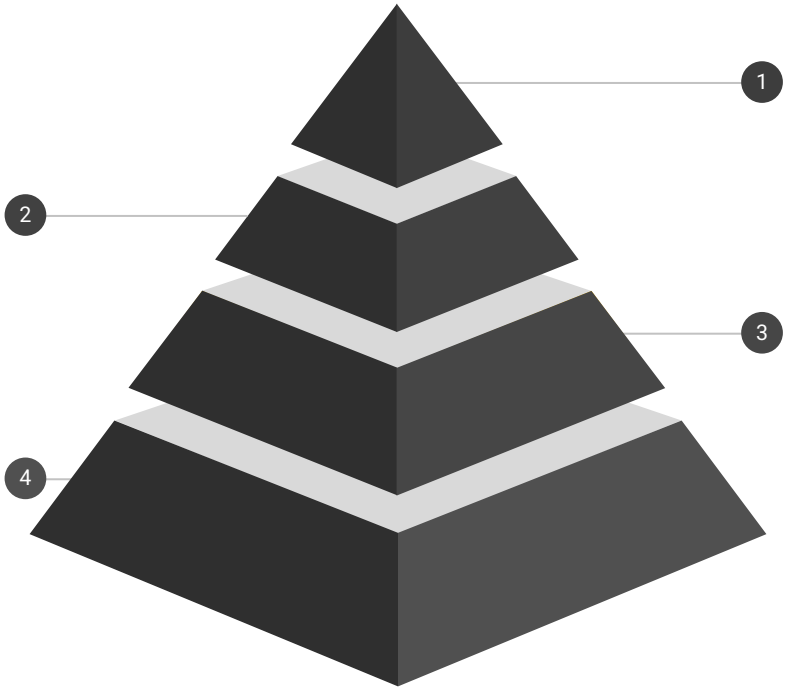
vlad.stirbu@compliancepal.eu

Outline

- Background and motivation
- 3rd party software
- Machine Learning (ML) in certified medical systems
- Conclusions

Certified medical systems

Medical regulatory landscape



Legislation

Applies to the entire market area. MDR in EU or FDA in US

Guidances

Communicates the expectations of the regulatory authorities and current practice for supporting implementation

Local legislation

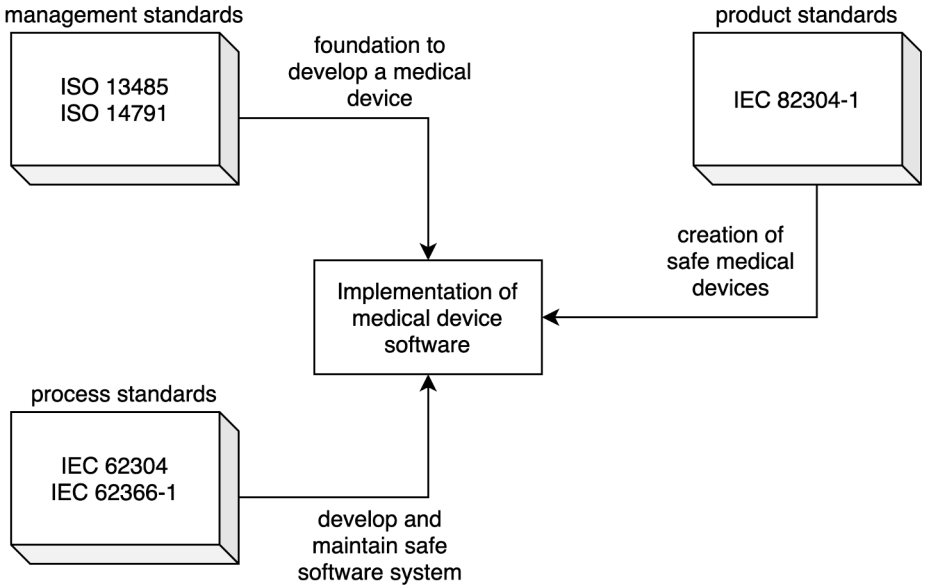
State level legislation that augments the market legislation

International standards

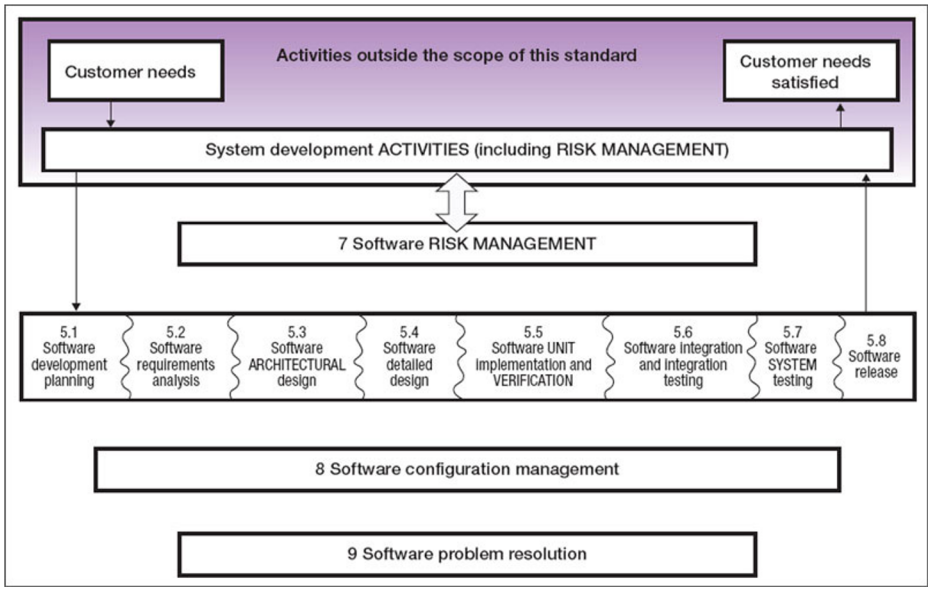
International standards (ISO and IEC) identified by regulatory authorities that allow manufacturers to declare conformance with relevant regulations

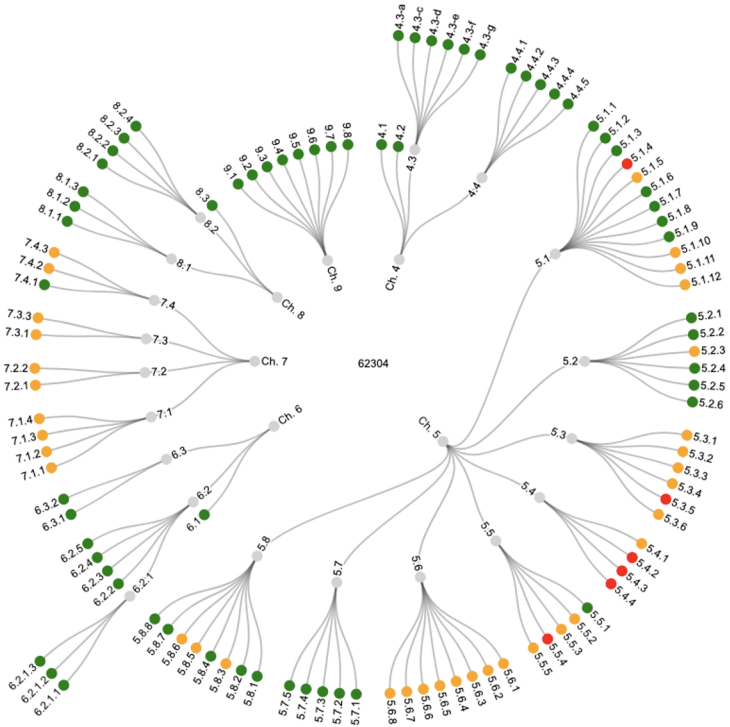
Standards

- Quality management system
- Risk management
- Product and software development lifecycle



Medical software development lifecycle (ISO 62304)



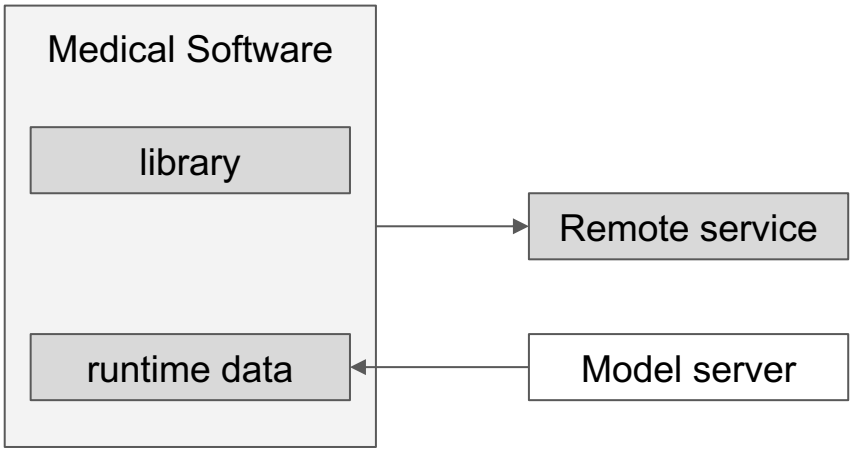


Safety risk classes: no harm (A), harm (B), serious harm or death (C)

Software of unknown provenance (SOUP)

Software that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as “off-the-shelf software”)

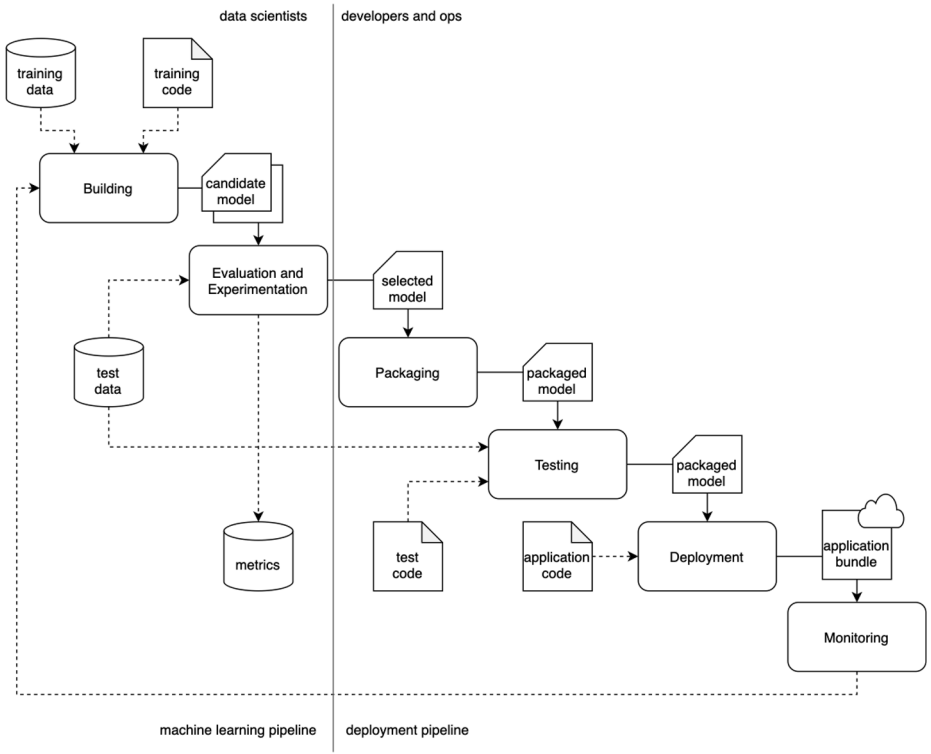
Software previously developed for which adequate records of the development processes are not available



Risk management for ML applications

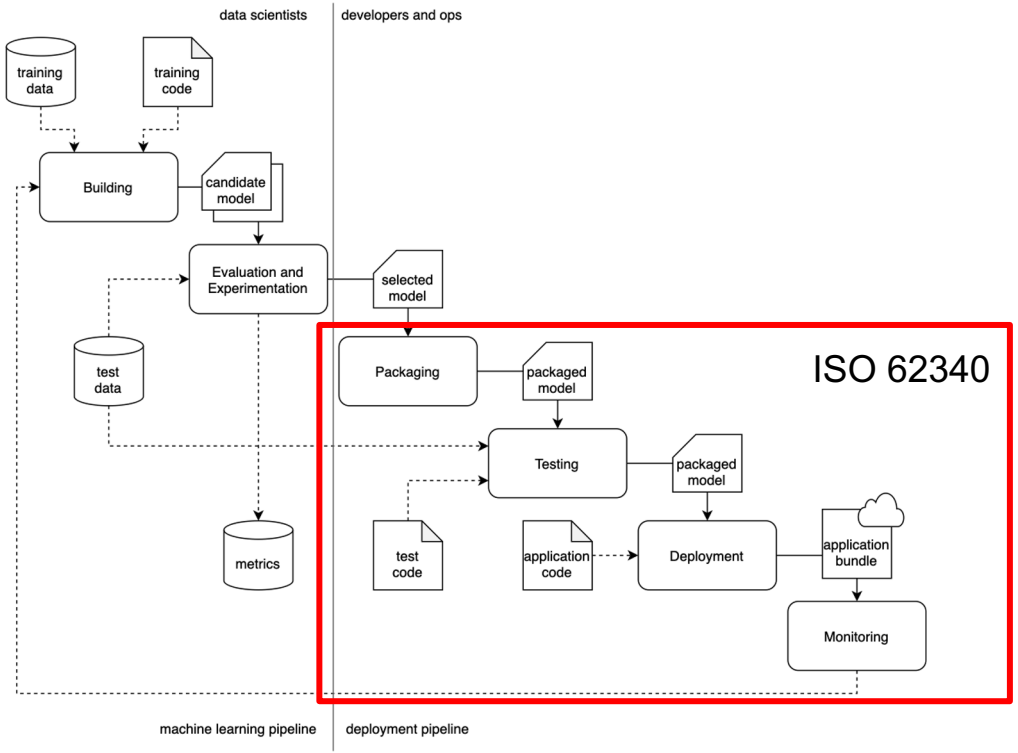
Input data	Algorithm design	Output decisions
Training and the normal use data mismatches	Human biases - flawed outputs Technical flaws - rigour and conceptual soundness Usage flaws Security flaws - delivebate flawed outputs by input manipulation	Incorrect interpretation and use of of the output

Machine learning development lifecycle



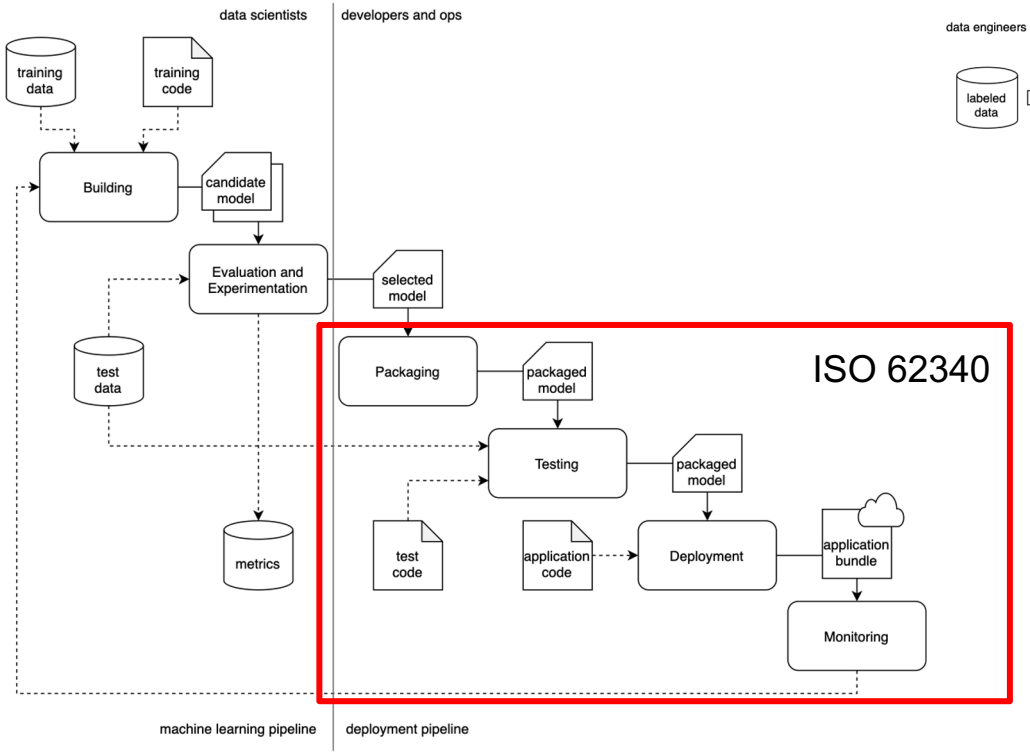
CD4ML

Machine learning development lifecycle



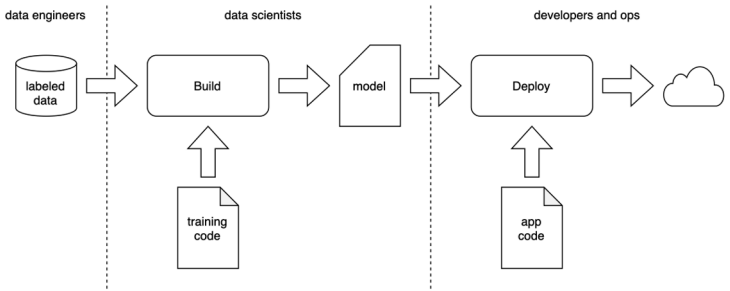
CD4ML

Machine learning development lifecycle



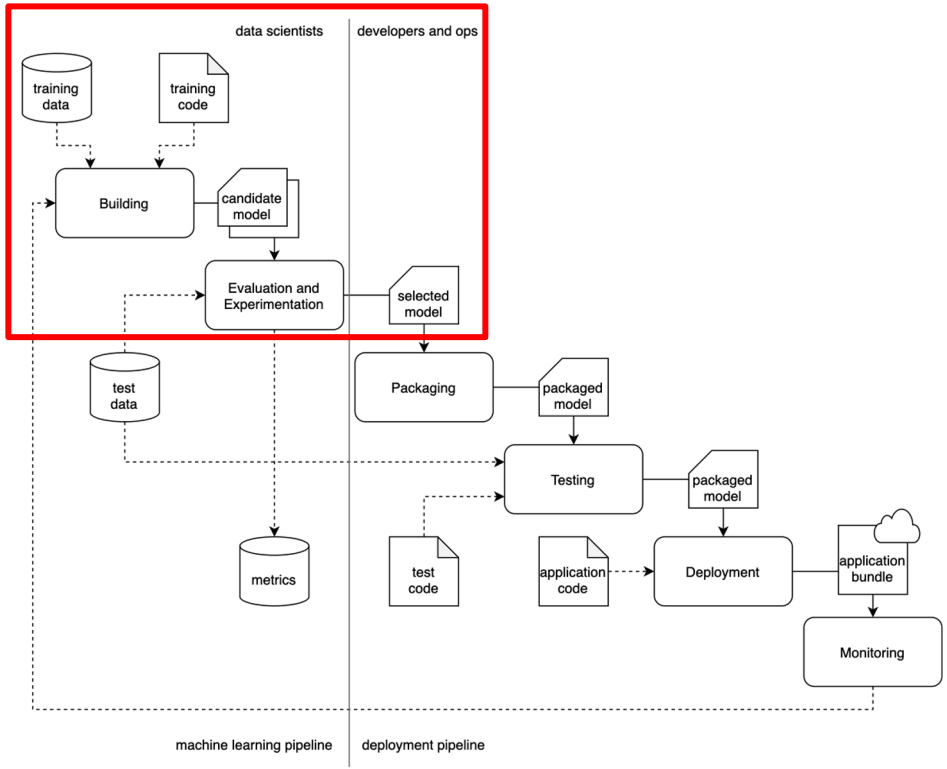
ISO 62340

CD4ML



Functional barriers

Extending the SOUP to ML model



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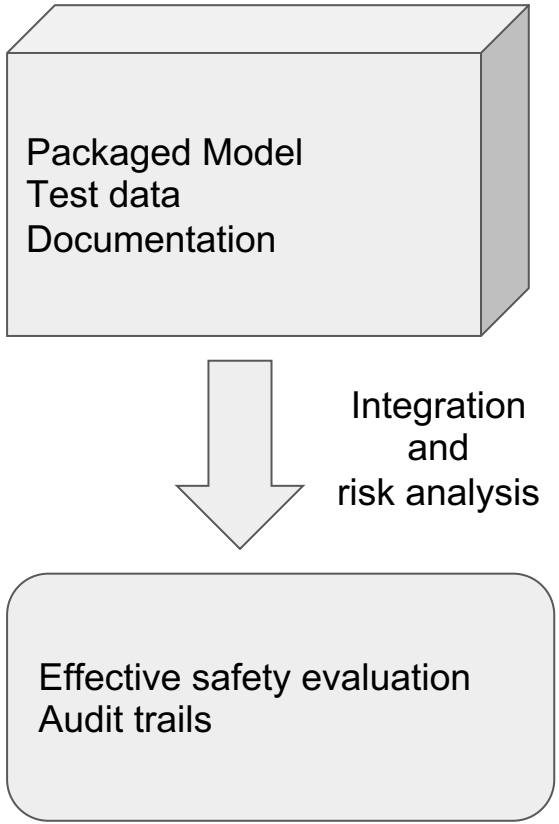

Conclusions

- Machine learning enable complex prediction systems
- Opaque and difficult to comprehend
- Must be handled with the same rigour as SOUP
- Establish solid guidelines codified in DevOps/MLOps pipelines
- Increased complexity on the regulatory activities