

Certification and Assurance Cases

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Terminology

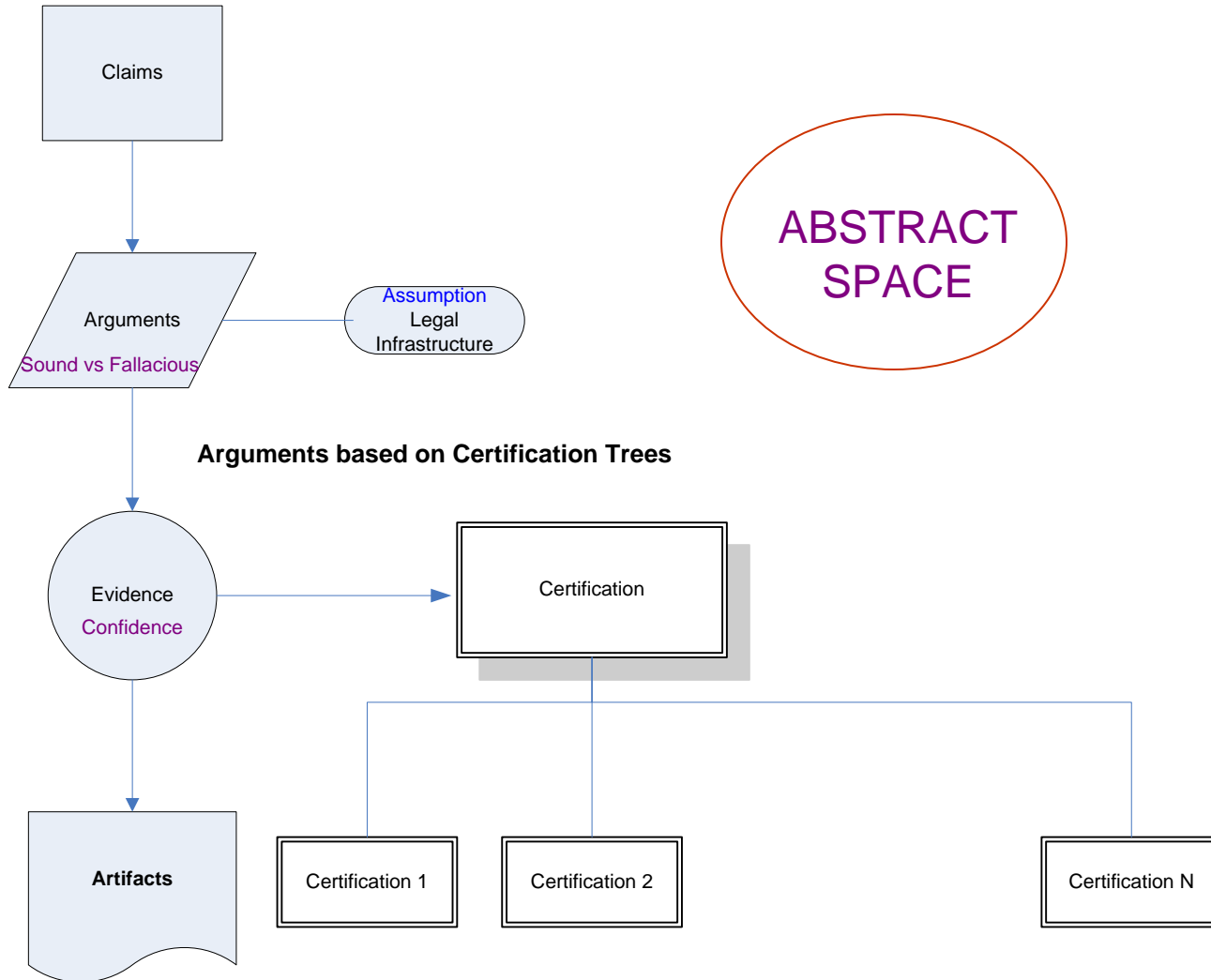
Certification:

Officially recognize (someone or something) as possessing certain qualifications or **meeting certain "standards"**.

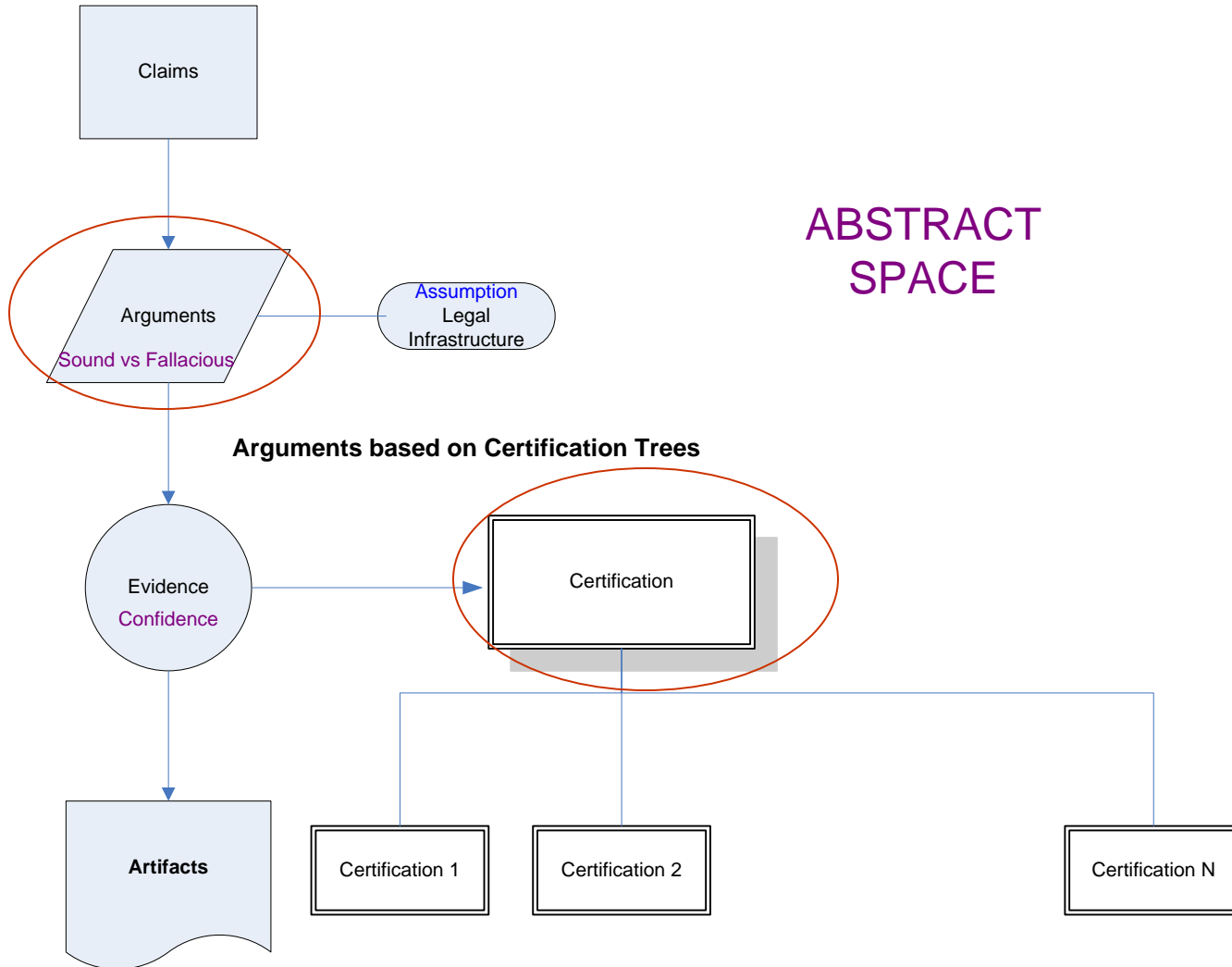
Evidence:

In its broadest sense includes everything that is used to determine or demonstrate the truth of an assertion (claim).

Assurance Case Framework



Assurance Case Framework

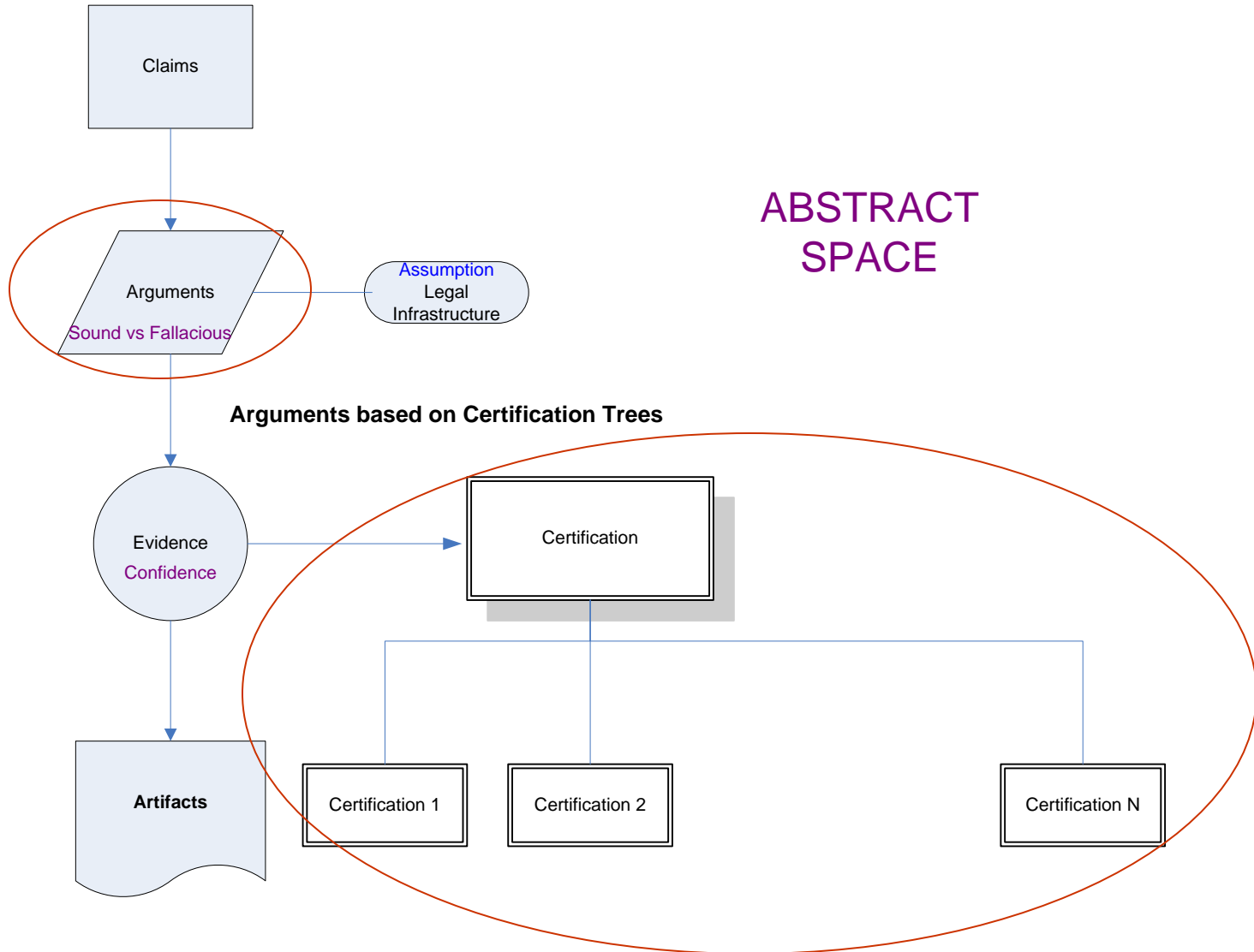


Certification based arguments

Specious / Fallacious argument based on a
Certification

We have been certified as conforming to
ISO 9001 therefore we produce quality
products + a certification letter.

Assurance Case Framework



Certification based arguments

Specious / Fallacious arguments based on certifications

We conform to the IEC 62304 medical device SDLC process standard therefore our medical device software is safe

[in addition]

We conform to the ISO 14971 medical device risk management (process) standard therefore our device is "very" safe!

Certification based arguments

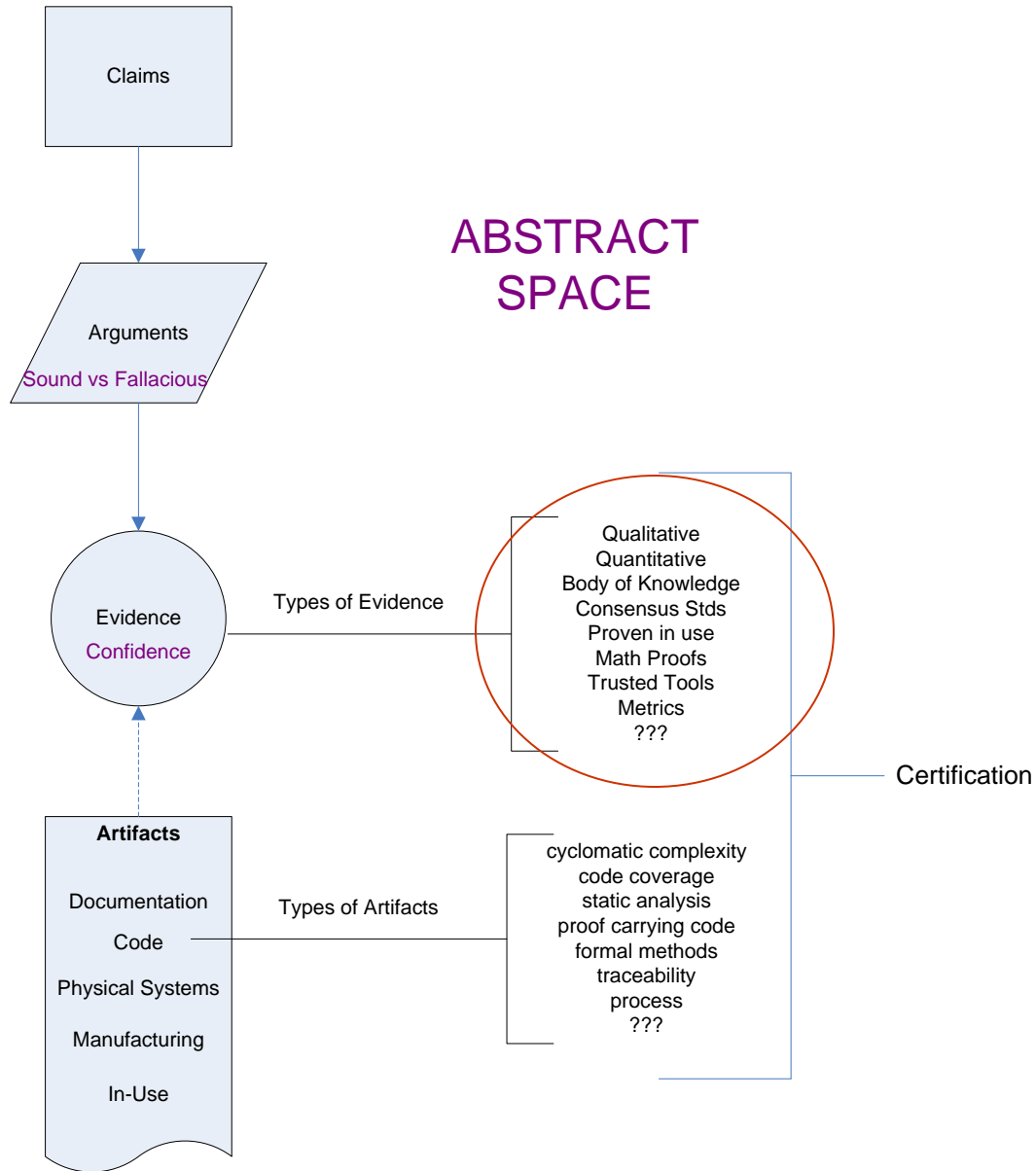
Trustable argument based on certification

Our attachment plugs and receptacles are electrically safe because they conform to the UL 498 standard + letter of certification from Underwriters Laboratories.

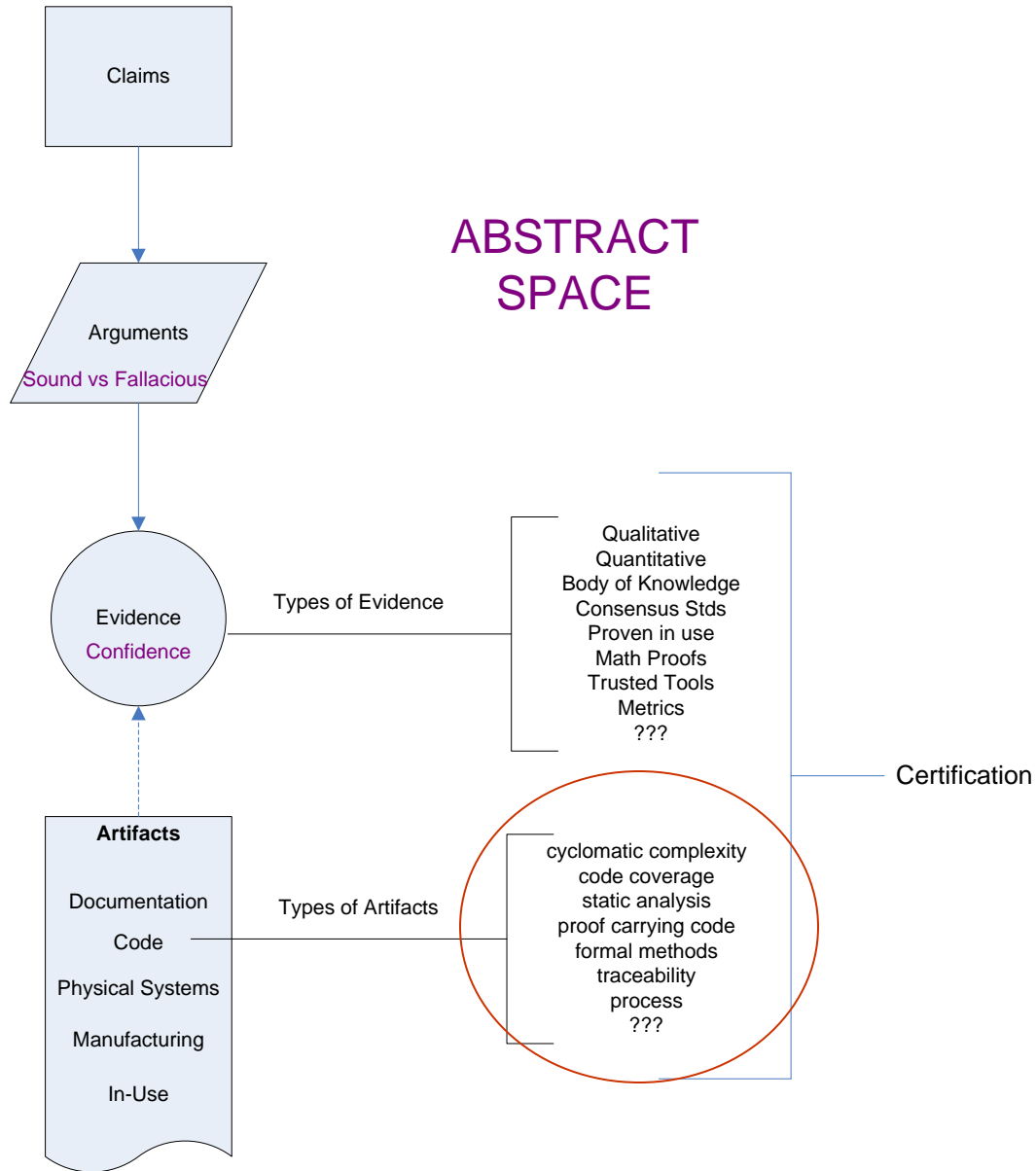


What can be certified about
software?

Assurance Case Framework



Assurance Case Framework



Conclusion 1

Regulators need well defined certification protocols and legal infrastructure to enable trust in assurance cases which are necessarily abstract.

Conclusion 2

Need to evolve software engineering to include trusted tool chains, principled practices, and meaningful metrics that establish trustable evidence as a product is developed and maintained.