Breakfast seminar

The standards jungle

QAdvis seminar Stockholm/Lund

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QAdvis key competence areas

QMS in-the cloud

Turn key QMS
Digital signatures
Efficient and lean
Validated and compliant

System development

Project management
Product software validation
Regulated software validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting

Interim management
Expert advise
Audits/Mock audits/Due diligence
Warning letters, compliance projects
PMA, 510k, CE-mark
Global regulatory support
Vigilance, recall, post market surveillance
Clinical evaluation and clinical studies

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Training/courses

CE-marking
ISO 13485 & 21CFR820
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
SW life cycle
SW risk management
Risk management
And more…

Lean and Six Sigma

Training and Consulting
In cooperation with USA based partner.

European Authorized Representation

Providing European representation for non-EU MedTech companies

Active board member of EAAR: European Association of Authorised Representatives

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QAdvis team

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Presentation of the speaker Mikael Dahlke

- 30+ years in SW and systems development
- 20+ years in Medical Device SW
- Participated in > 20 audits, FDA, MDD, etc.
- Certified Lead auditor (ISO 13485)
- Senior Systems and Quality consultant
- Electromedical Devices architecture expertise
- Risk management expertise
- Has implemented several quality management systems
- Member of SEK TK62 (60601 and related standards)
- Member of ISO TC215/IEC SC62A JWG7 (62304)

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Agenda

- Why standards?
- Where do they come from?
- How they are named
- Hot topics in Europe
- Practical examples

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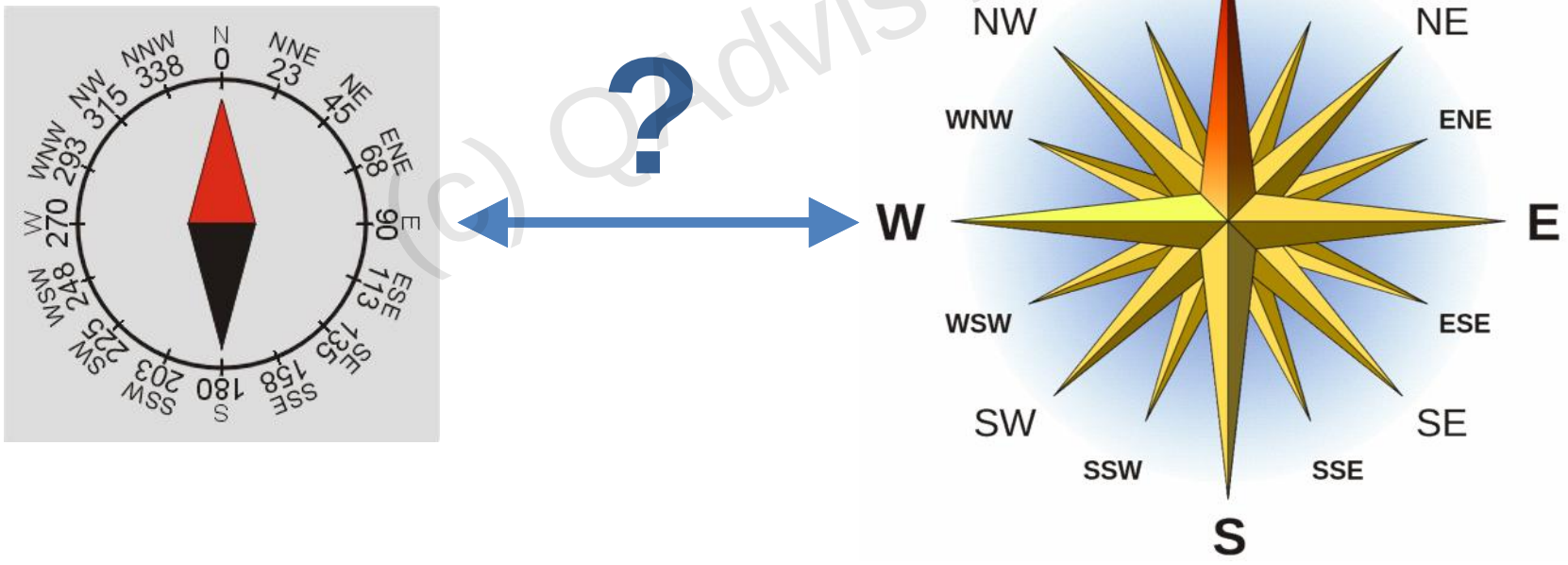
Lost in the standards jungle?

- Confusing list of standards - directives



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Why standards?

- Reuse of knowledge
- Risk reduction
- Harmonize technical regulation

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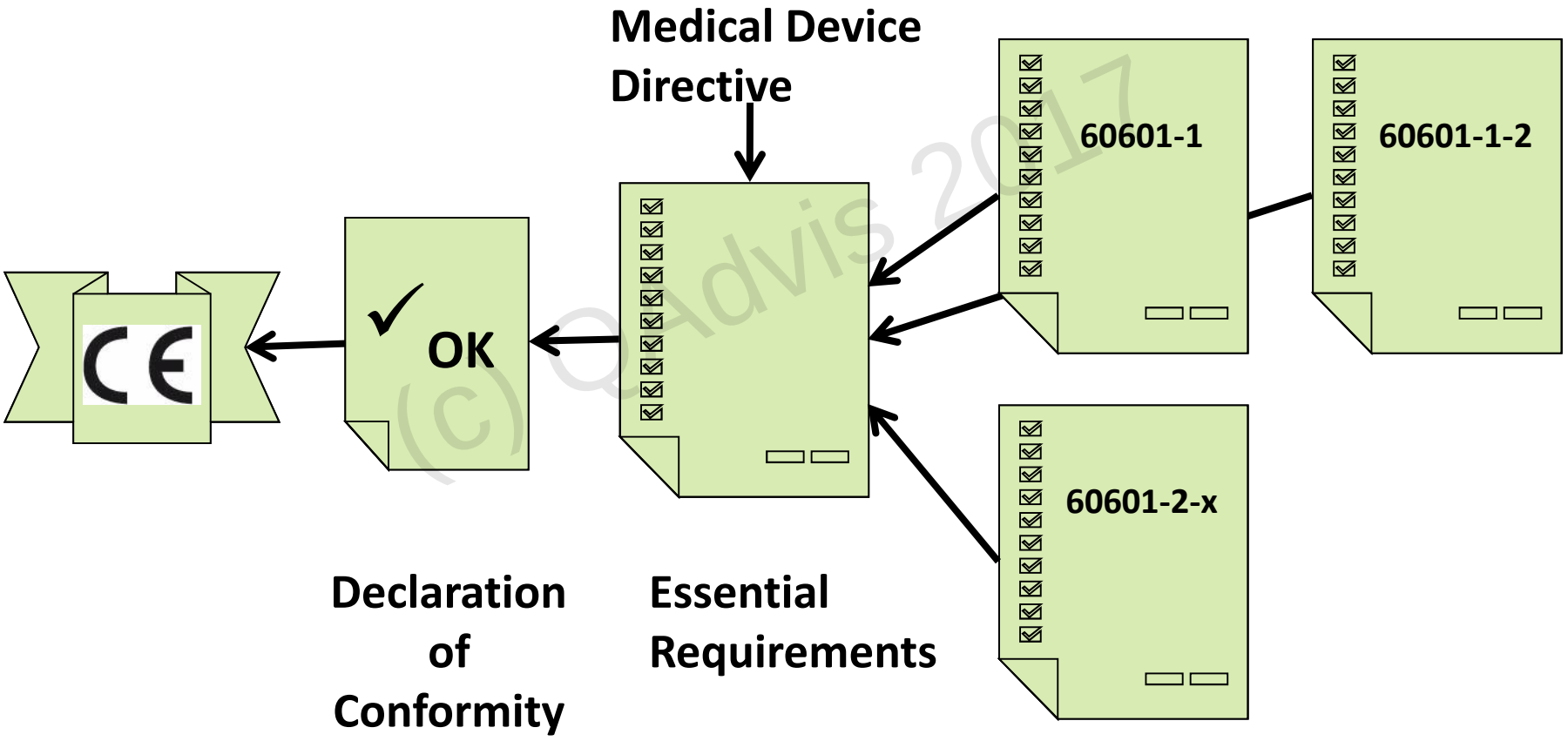
Where does the CE mark come from?



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Governments and Agencies are enforcing new regulation across time

EU-Commission/US Government
IVDD / AIMD / MDD / Public Health Service Act

Agencies
Medical Products Agency / FDA

Laws and Regulations
SFS 1993:584 / 21 CFR 820

Guidance documents
Standards – 13485, 14971, 62304

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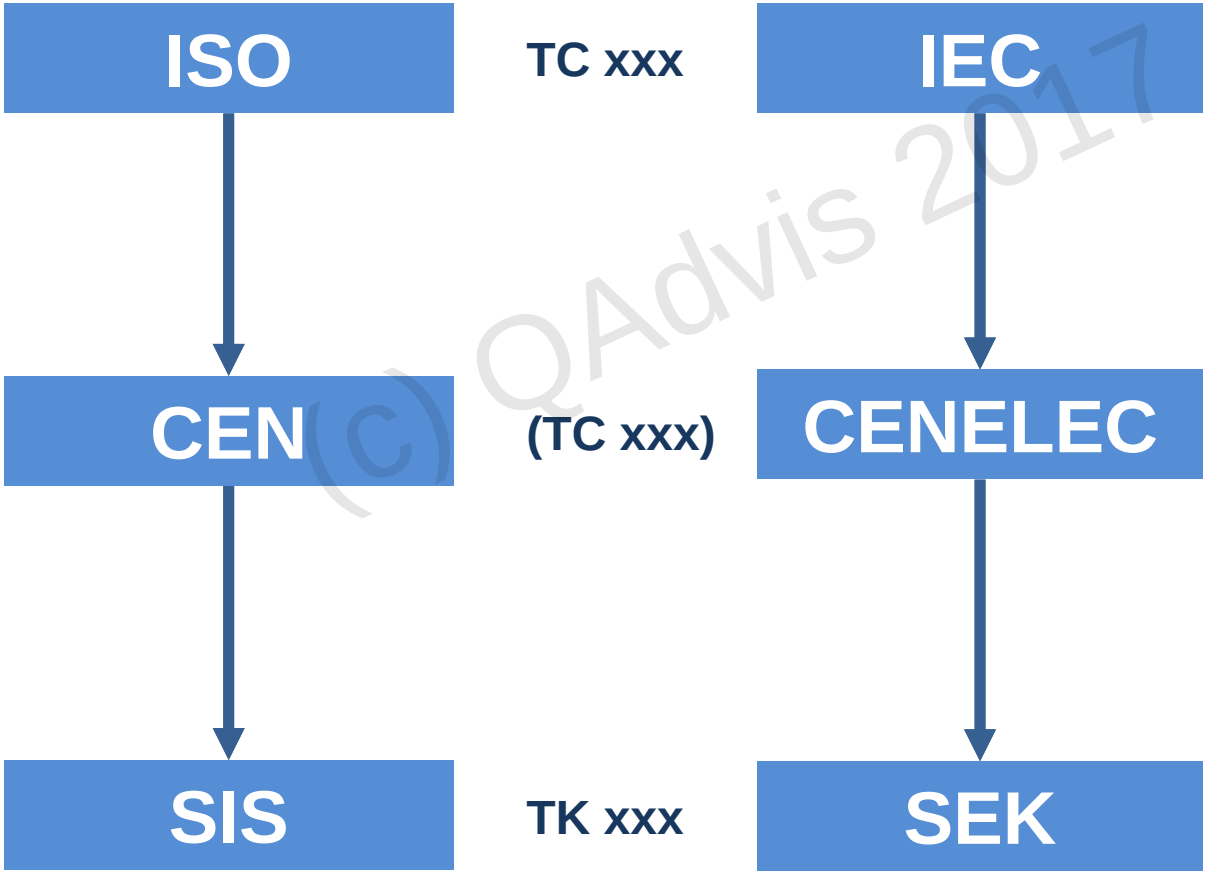
Who standardizes?



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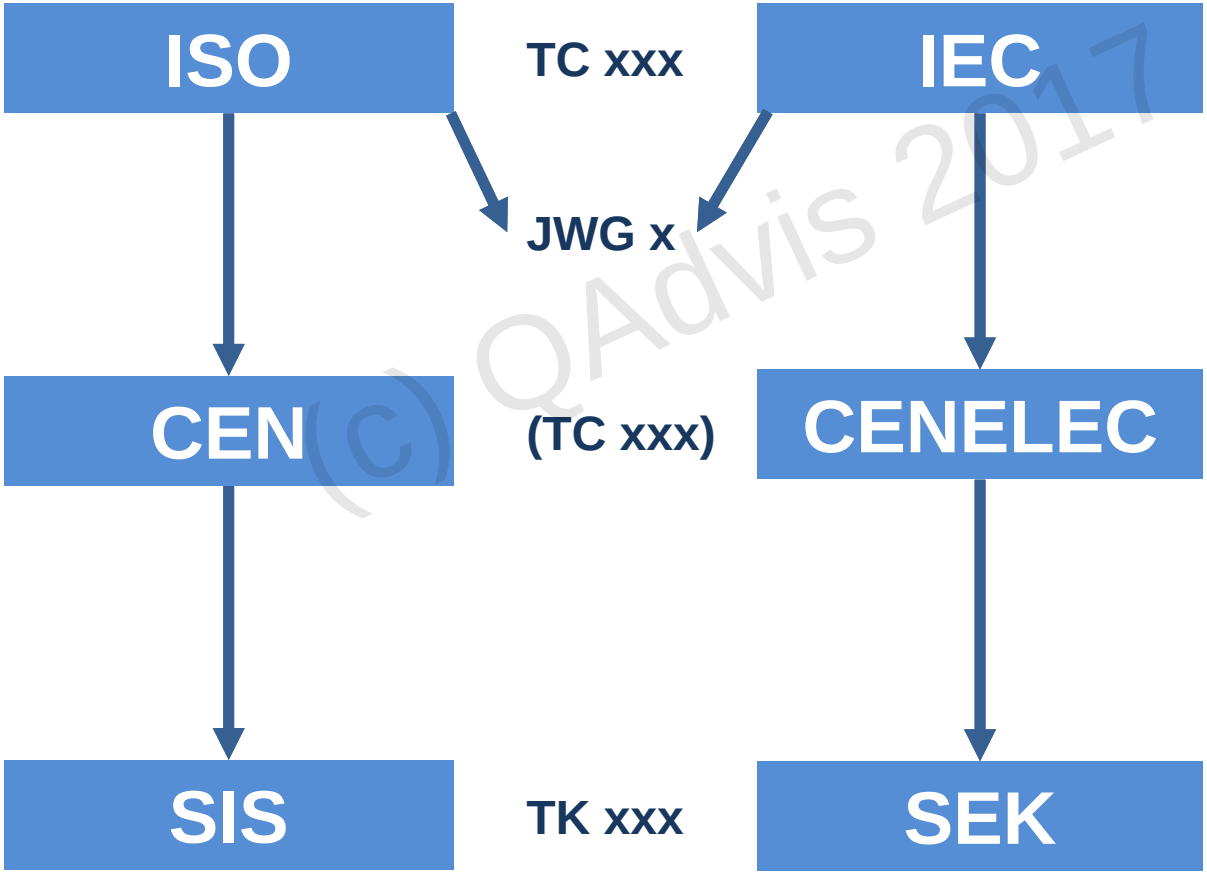
Who standardizes?



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Naming

ISO 13485

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EN ISO 13485

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SS-EN ISO 13485

IEC 60601-1

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EN 60601-1

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SS-EN 60601-1

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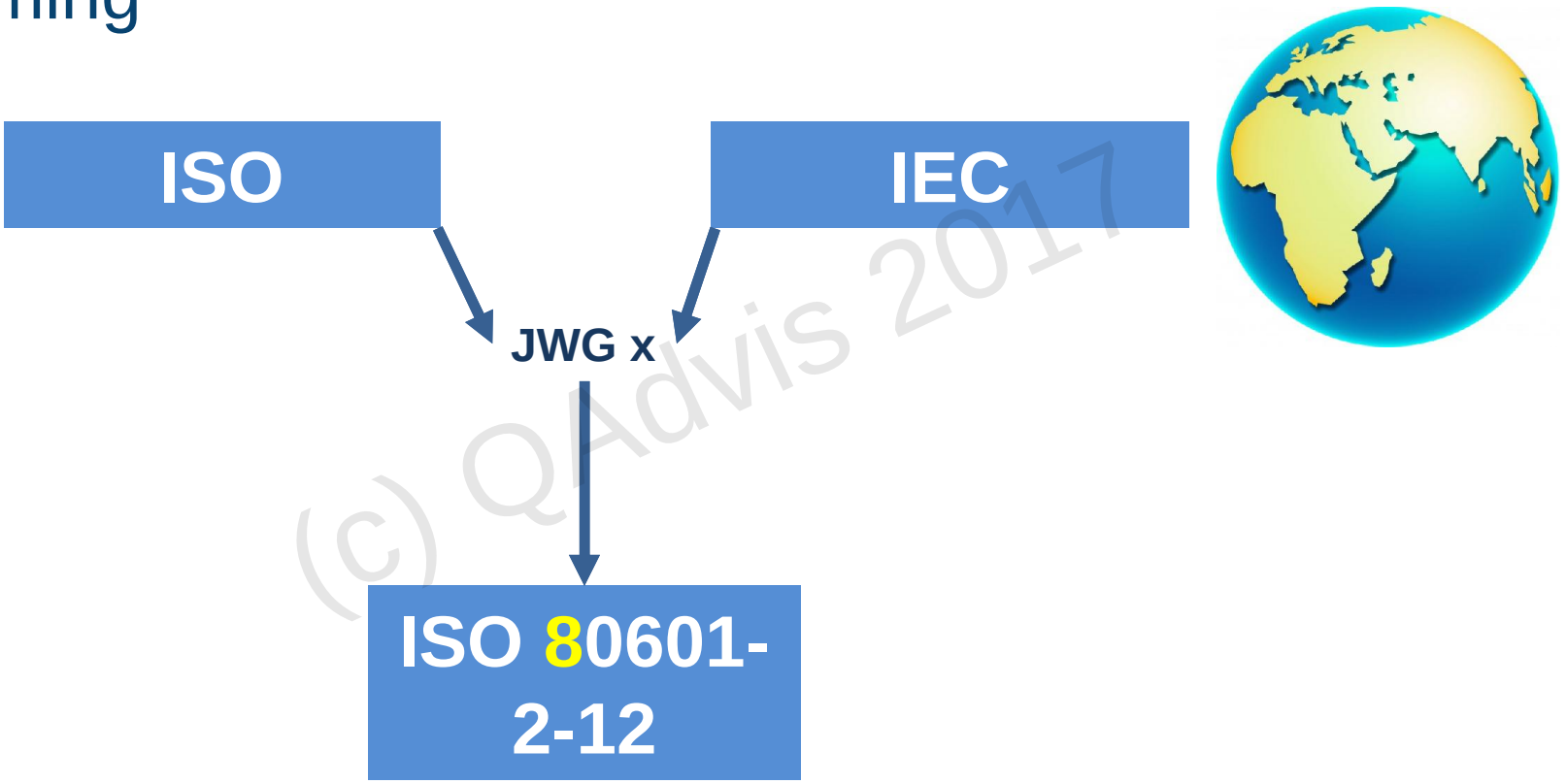
Naming



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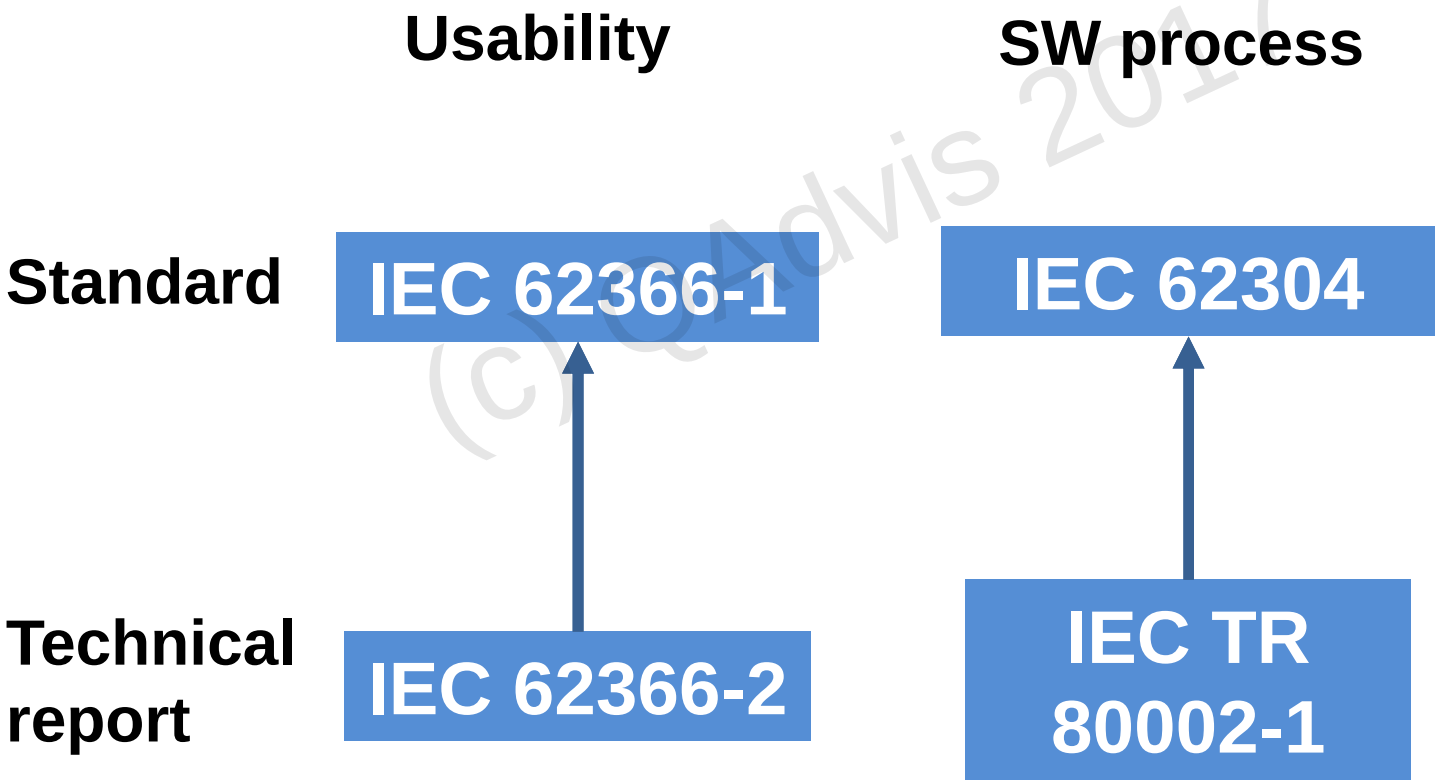
Standards and reports



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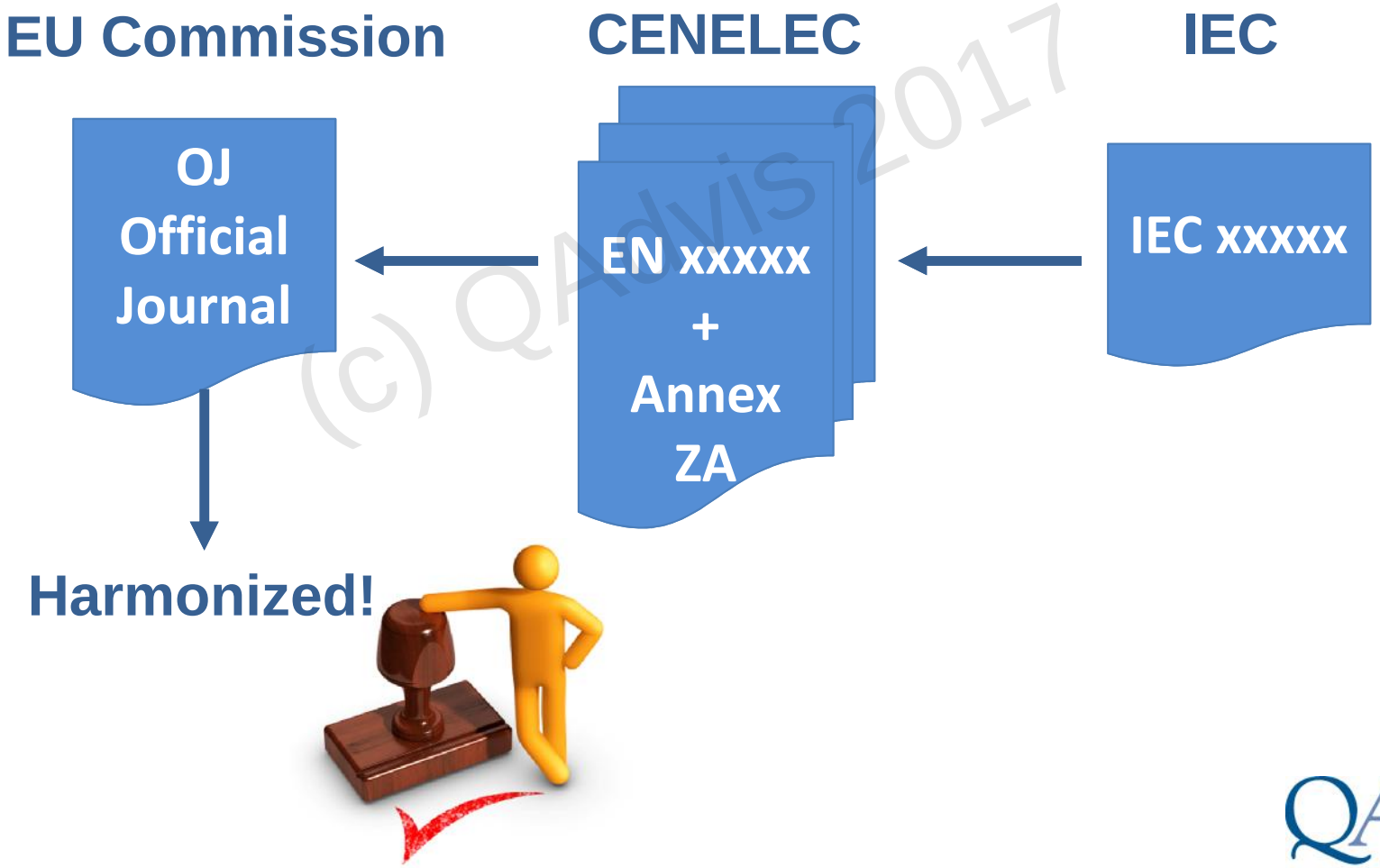
Rumble in the jungle…



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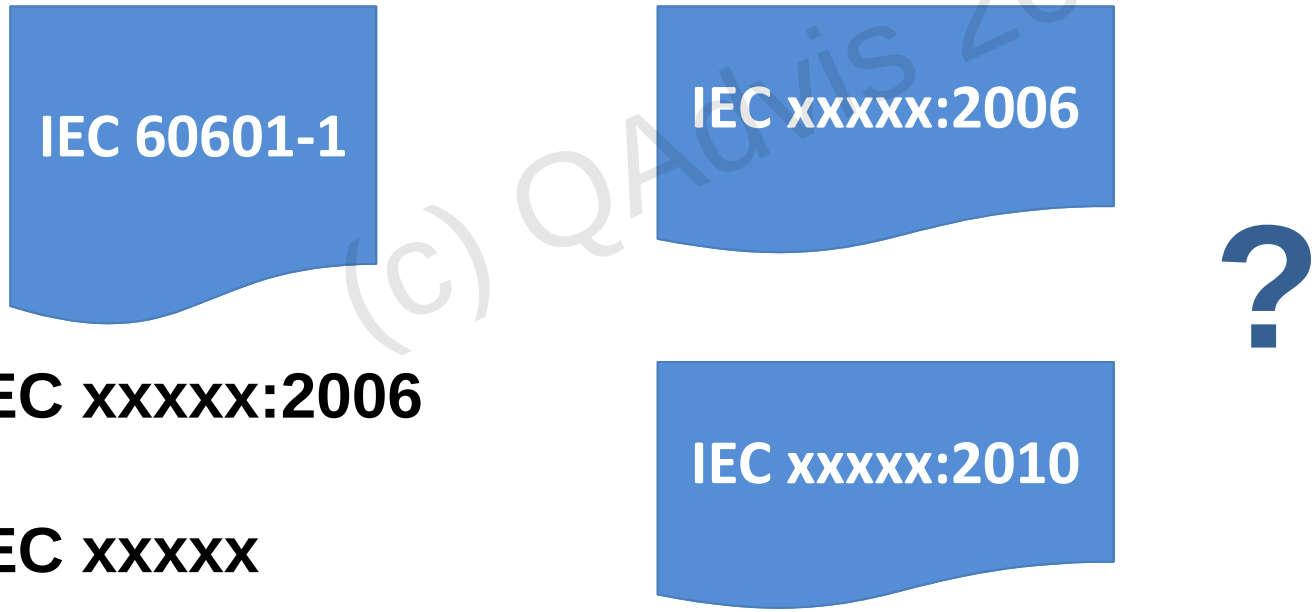
Rumble in the jungle…



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Go west young man…

AAMI Association for the Advancement of Medical Instrumentation

AAMI TIR36 **Validation of SW for quality systems**

AAMI TIR45 **Agile practices in medical device SW**

ASTM International

ASTM F1980 **Accelerated aging of sterile barriers**

ASTM D4169 **Testing of Shipping Containers**

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Main process standards

- ISO 13485 Quality management system
- ISO 14971 Application of risk management to medical devices
- ISO 10993 Biological evaluation of medical devices
- IEC 62304 Software life cycle processes
- IEC 62366-1 Application of usability engineering to medical devices

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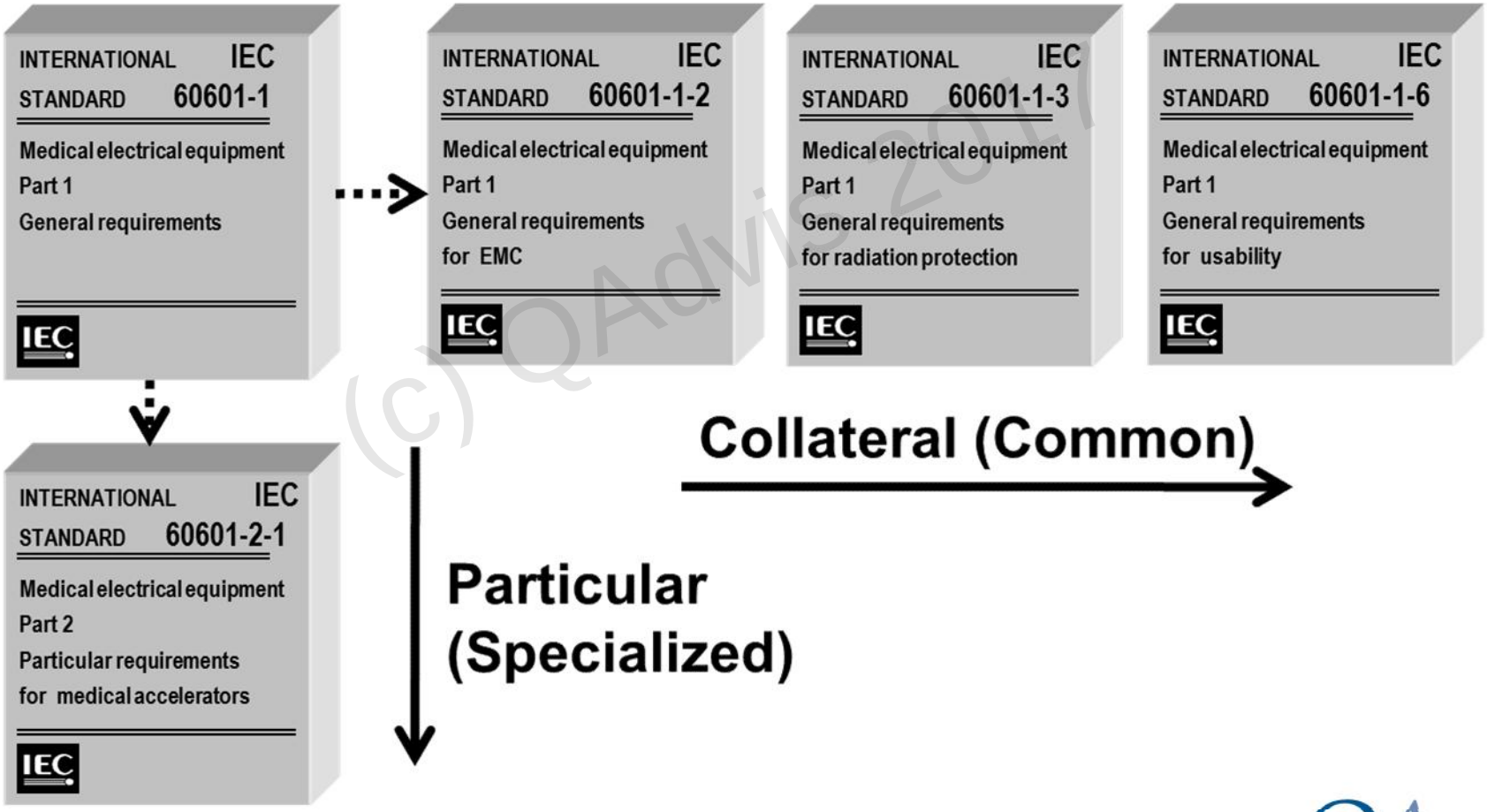
Collaterals and particulars…



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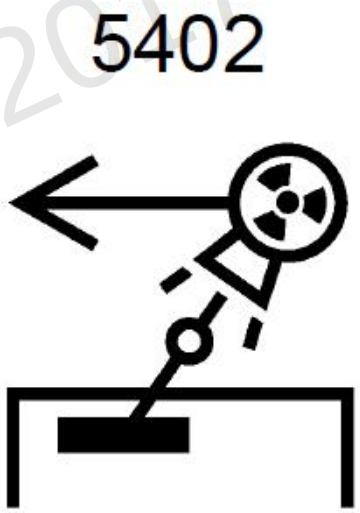
And some extras

5.1.4

Indicates the date after which the medical device is not to be used.

ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied



Tomographic movement with X radiation

IEC/TR 60878: Graphical symbols for electrical equipment in medical practice

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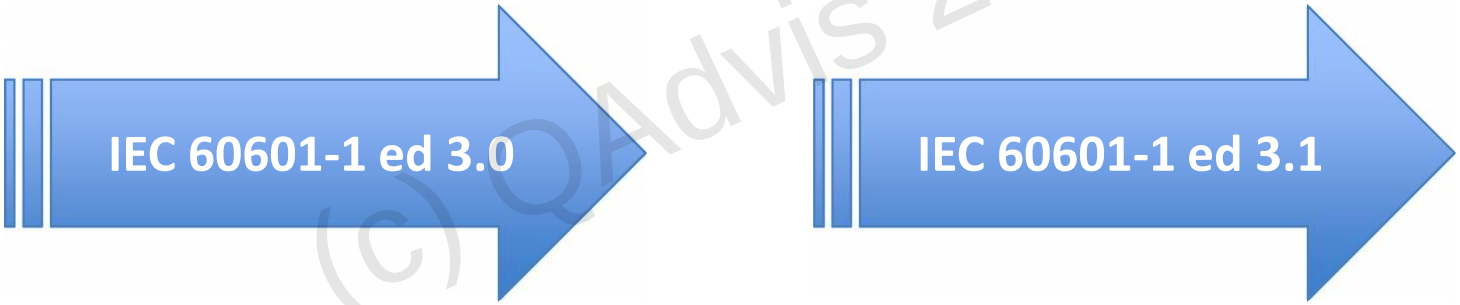
Transition times– the fine print



2012 **2018**

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The world outside EU

USA

FDA Recognised consensus standards

China, Japan, Korea…

Check acceptability of standards

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Example: Electromedical device for home use

- IEC 60601-1
- IEC 60601-1-2 EMC
- IEC 60601-1-6 Usability
- IEC 60601-1-8 Alarm systems
- IEC 60601-1-11 Home healthcare environmer
- IEC 60601-2-x Product specific

Product

- ISO 13485 Quality management system
- ISO 14971 Risk management
- ISO 10993 Biological evaluation
- IEC 62304 Software life cycle processes
- IEC 62366-1 Usability

Process

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Example: In vitro diagnostic device

- IEC 61010-1
- IEC 61010-2-101 vitro diagnostic (IVD) medic equipment

Product

- ISO 13485 Quality management system
- ISO 14971 Risk management
- IEC 62304 Software life cycle processes
- IEC 62366-1 Usability

Process

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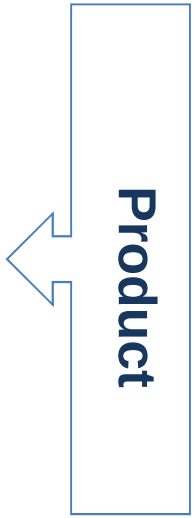
Example: SaMD (Software as a Medical Device)

- IEC 82304-1 Health software – General requirements for product safety



- ISO 13485 Quality management system
- ISO 14971 Risk management
- IEC 62304 Software life cycle processes
- IEC 62366-1 Usability

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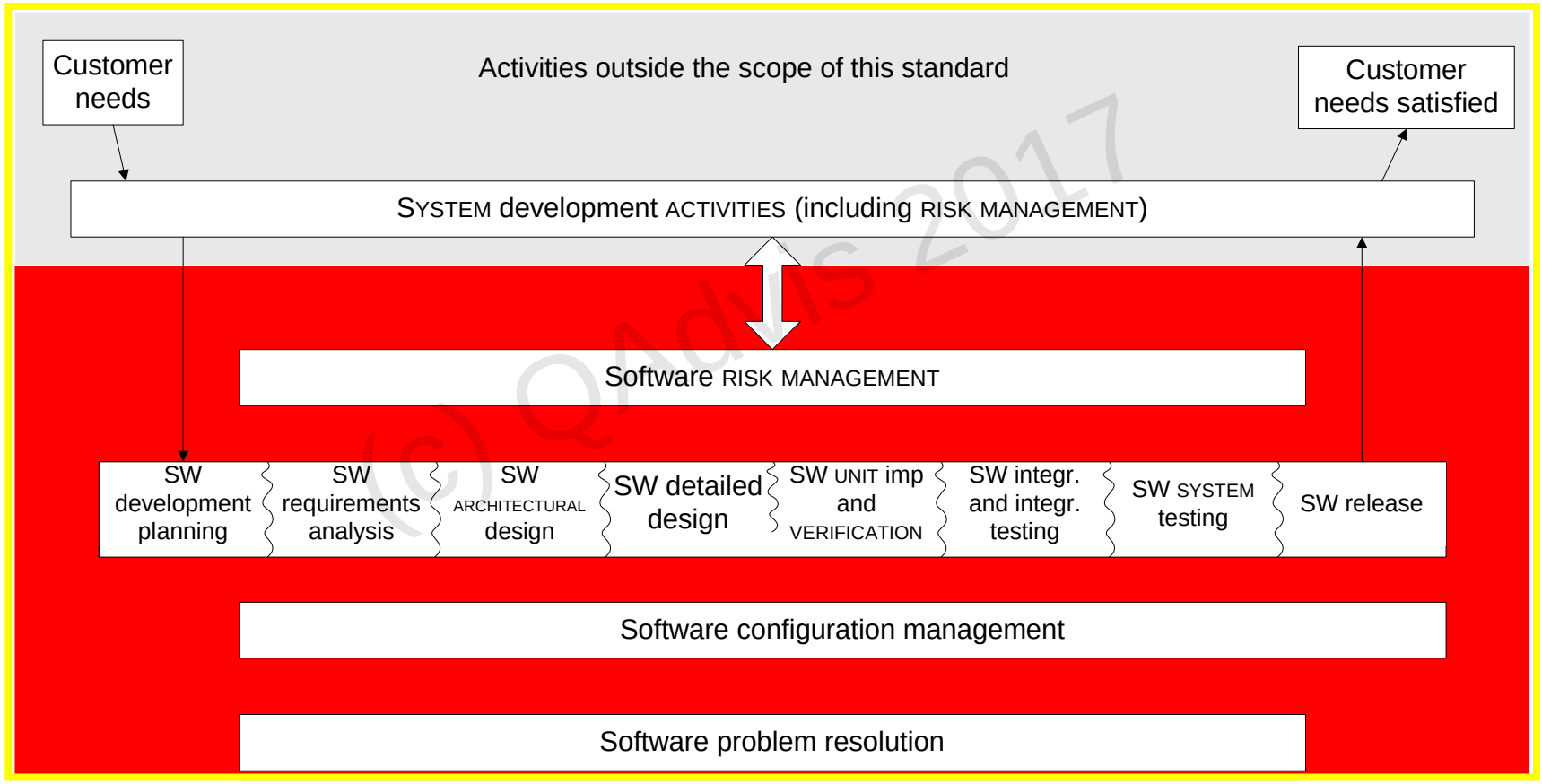
The structure of 62304 is aligned with system level standards, IEC 60601-1 or IEC 82304-1



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Product vs process standards

Analyzer instrument

IVD standards
IEC 61010-1
IEC 61010-2-x

Scanner

Electromedical device
IEC 60601-1
IEC 60601-2-x

Imaging workstation

Software as
Medical Device
IEC 82304-1

Product

Quality management system - ISO 13485
Risk management - ISO 14971
Usability engineering – IEC 62366-1
Software lifecycle processes - IEC 62304
Biocompatibility - ISO 10993

Process

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Test reports outside EU

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IEC 60601-1

CB scheme – (IECEE System)

Intertek

CB certificate

UL, CSA…

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-6
…

Test reports

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Thank you for your attention!
Questions & Answers

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QAdvis can support you as needed

- Identifying applicable standards for your development project
- Internal training
- Implementing a QMS
- Software Quality Assurance
- Internal audits
- Supplier audits

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