The standards jungle

The standards jungle
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QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

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Presentation of the trainer Mikael Dahlke

- 30+ years in SW and Systems Development
- 25+ years in Medical Device SW
- Participated in > 20 audits, FDA, MDD, etc.
- Certified Lead auditor (ISO 13485)
- Active member in standardization. SEK/TK 62 electromedical equipment and the international working group for SW in medical devices, JWG7. Member of 62304 ed 2 and two cybersecurity project teams.

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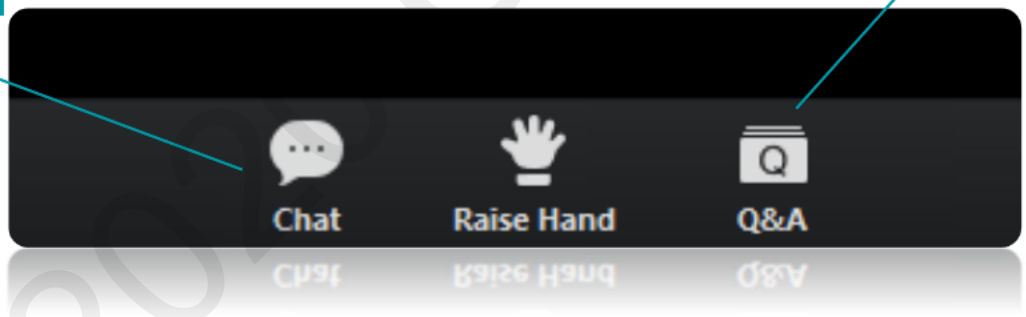
Practical issues

- Presentation will be recorded
- Questions answered after the presentation
- Short evaluation in the end

Zoom webinar

‘Chat’- used to get in touch with the administrator, will not be answered by the presenter.

Ask your questions, via ‘Q&A’.



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Agenda - seminar

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

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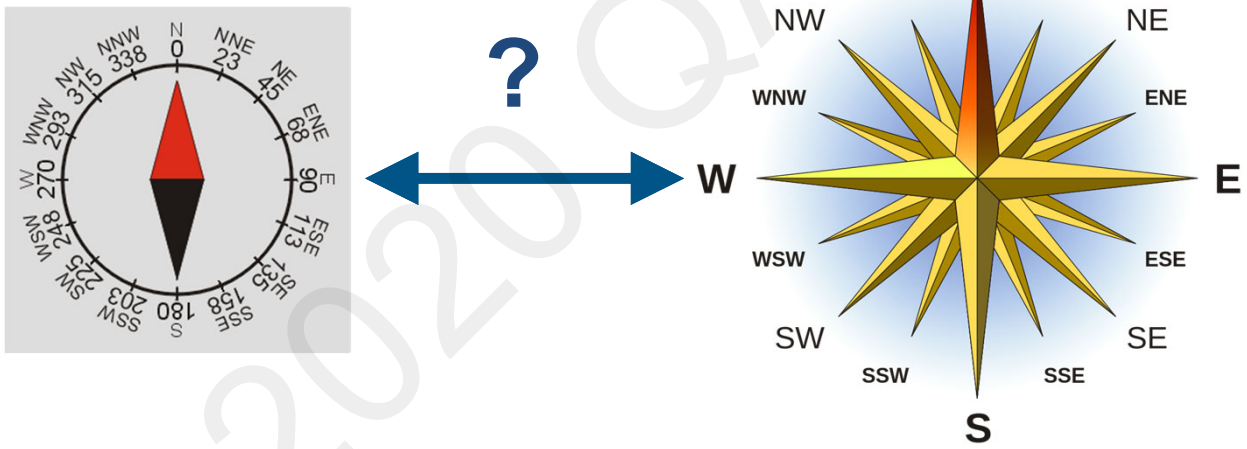
Lost in the standards jungle?

- Confusing list of standards - directives



Why standards?

- Reuse of knowledge
- Risk reduction
- Harmonize technical regulation

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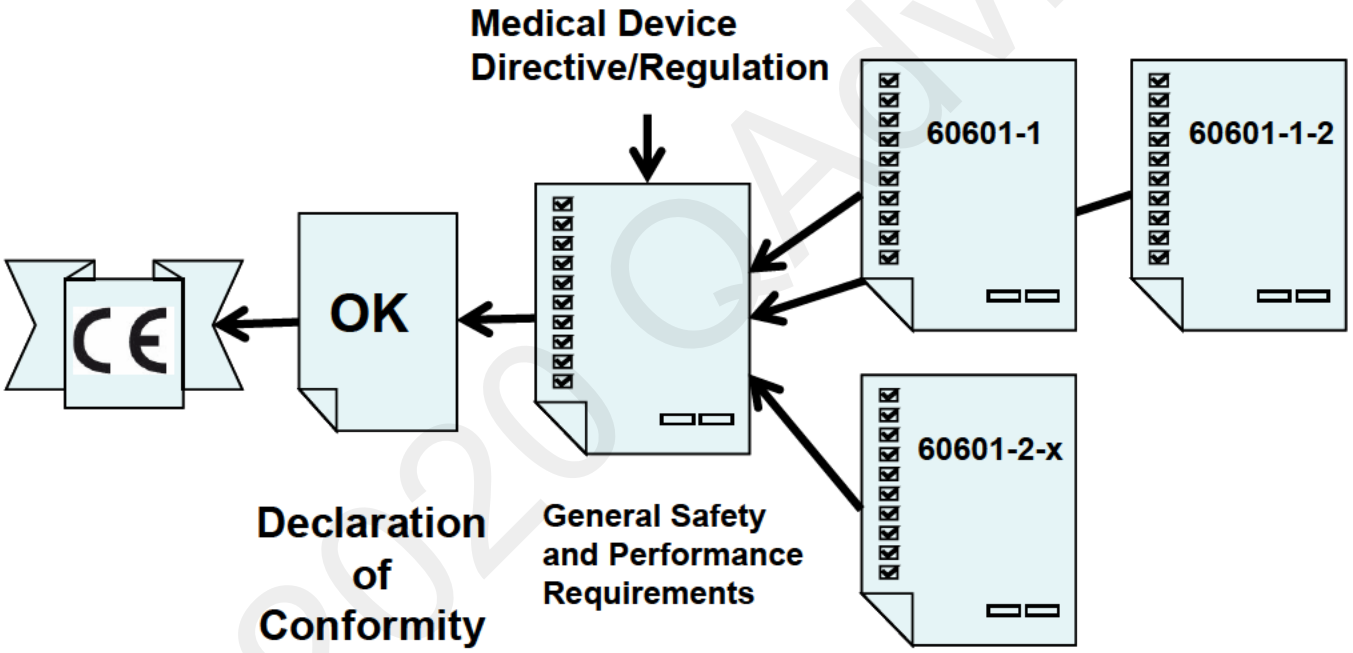
Where does the CE mark come from?



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Governments and Agencies are enforcing new regulation across time

EU-Commission
IVDD/AIMD/MDD
IVDR/MDR

US Government
Public Health Service Act

Agencies
Medical Products Agency
Läkemedelsverket

FDA

Laws and Regulations
SFS 1993:584

21 CFR 820

Guidance documents
Standards – ISO 13485, ISO 14971, IEC 62304

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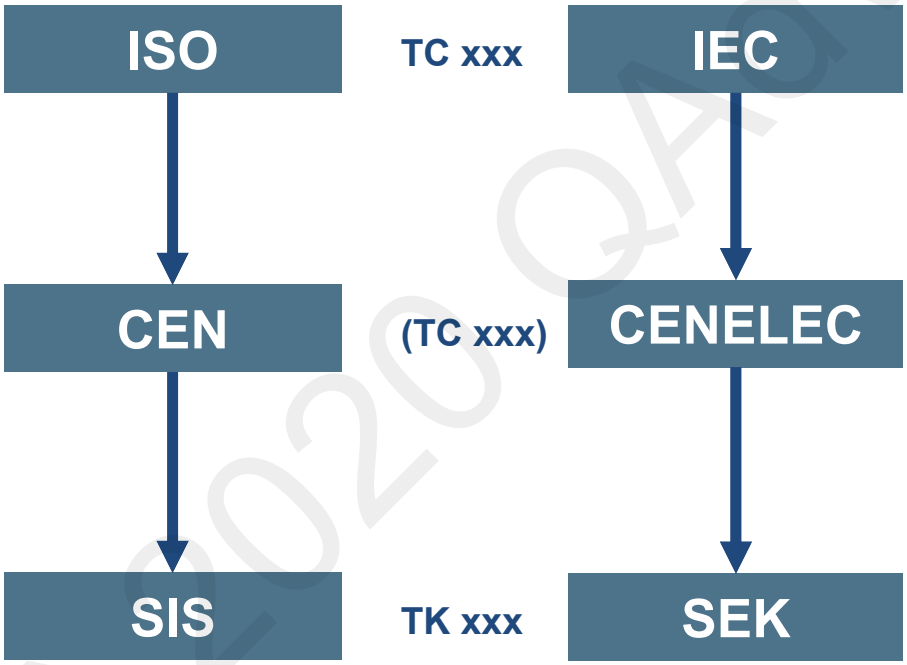
Who standardizes?



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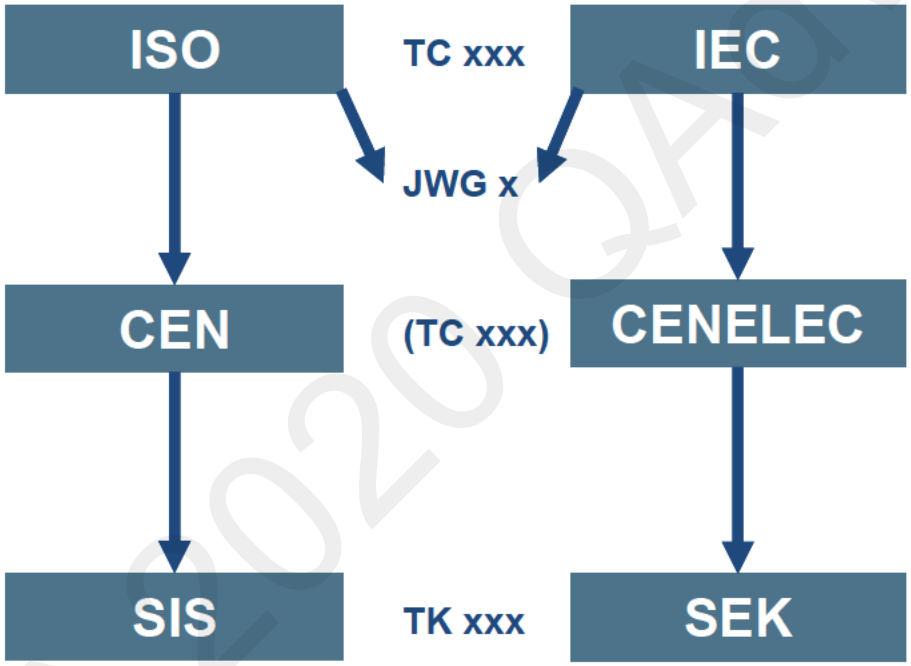
Who standardizes?



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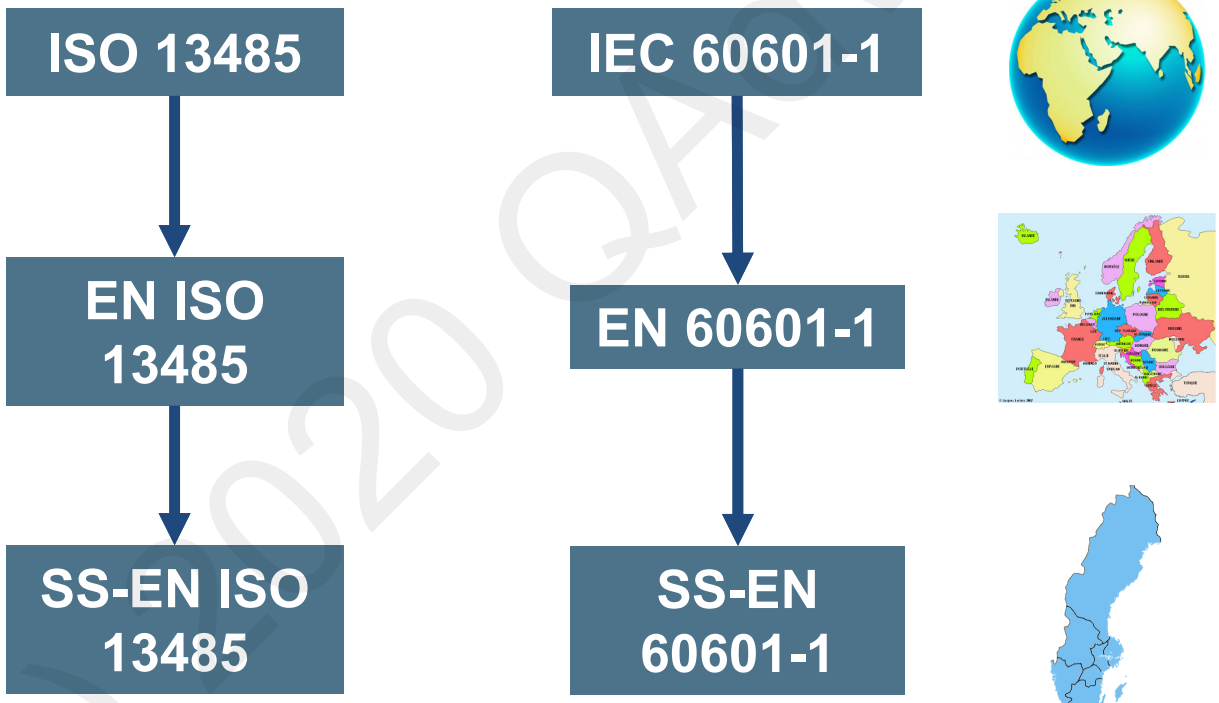
Naming



Naming

BS EN ISO 13485
DIN EN ISO 13485
NF EN ISO 13485

BS EN 60601-1
DIN EN 60601-1
NF EN 60601-1

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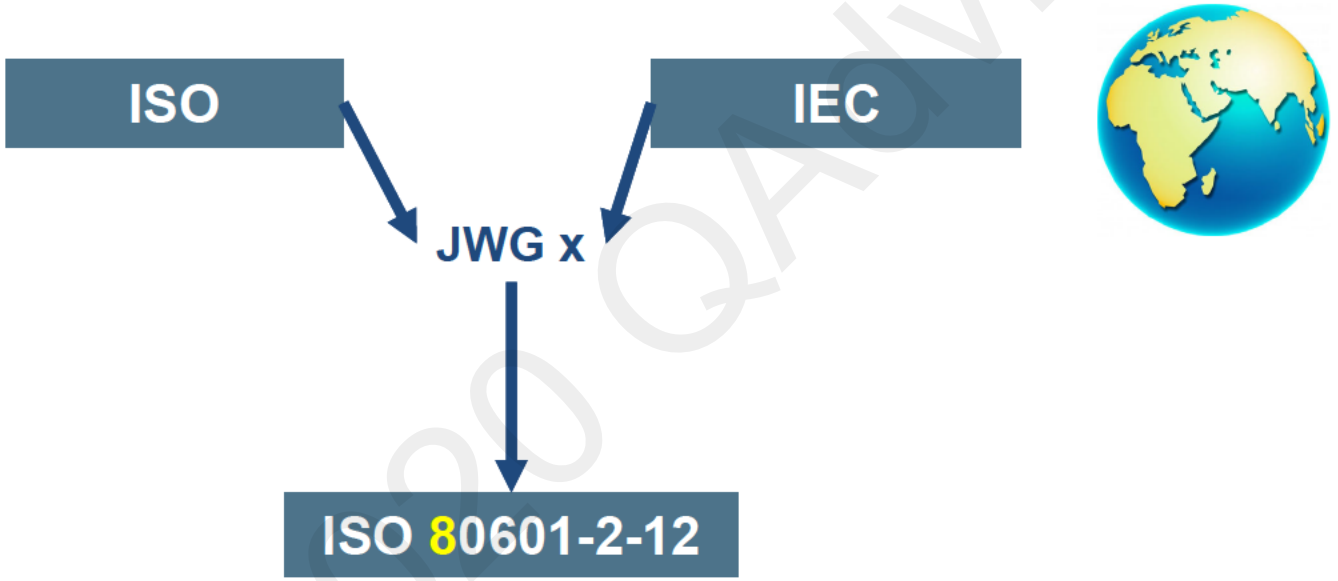
Naming



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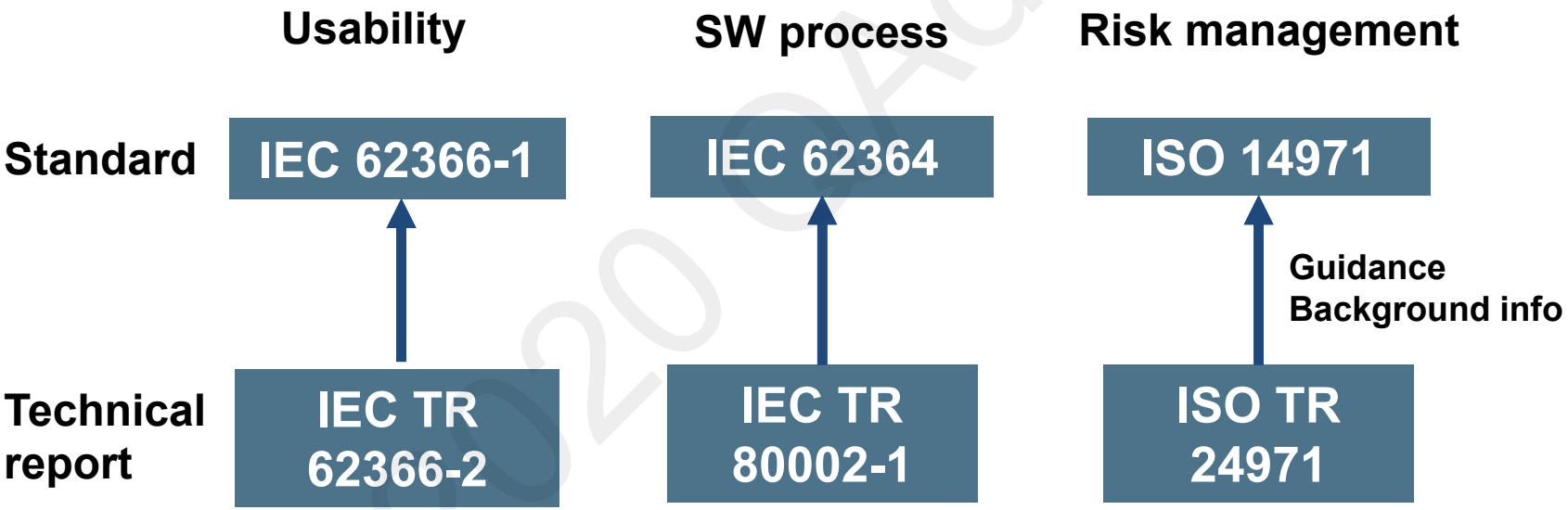
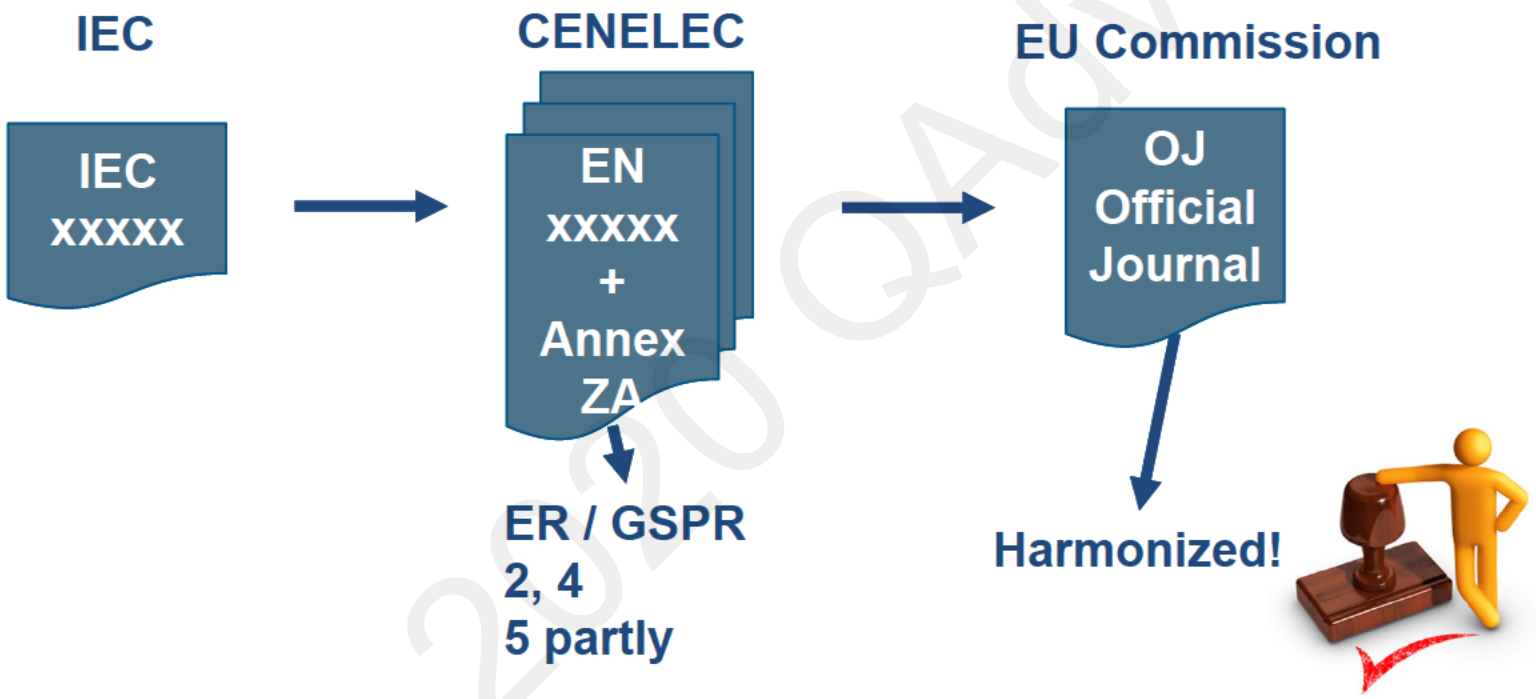
Standards and reports



Rumble in the jungle…



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Rumble in the jungle…

May 2021	
EN ISO 13485	Quality management systems
EN ISO 14155	Clinical investigation of medical devices
EN ISO 14971	Risk management
EN 15986	Labelling of medical devices containing phthalates
EN ISO 15223-1	Symbols

May 2024	
EN 556-x EN ISO 11737-x EN ISO 13408-x	Sterilization, cleaning
EN ISO 10993-x	Biological evaluation
EN ISO 22442-x	Medical devices utilizing animal tissues
EN 60601-1 EN 60601-1-x	Medical electrical equipment
EN 62304	Software
EN 62366-1	Usability engineering

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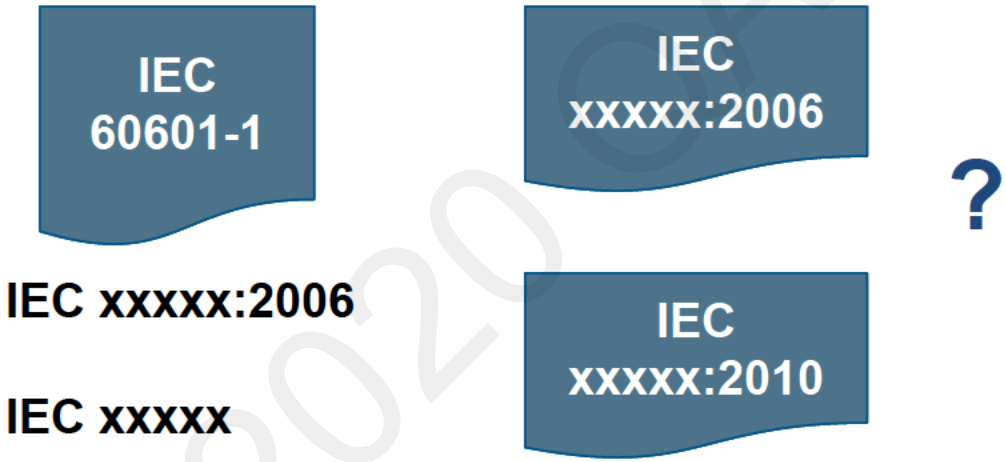
Age confusion…



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 80001-5-1 Security lifecycle processes*
- IEC 62366-1 Application of usability engineering to medical devices

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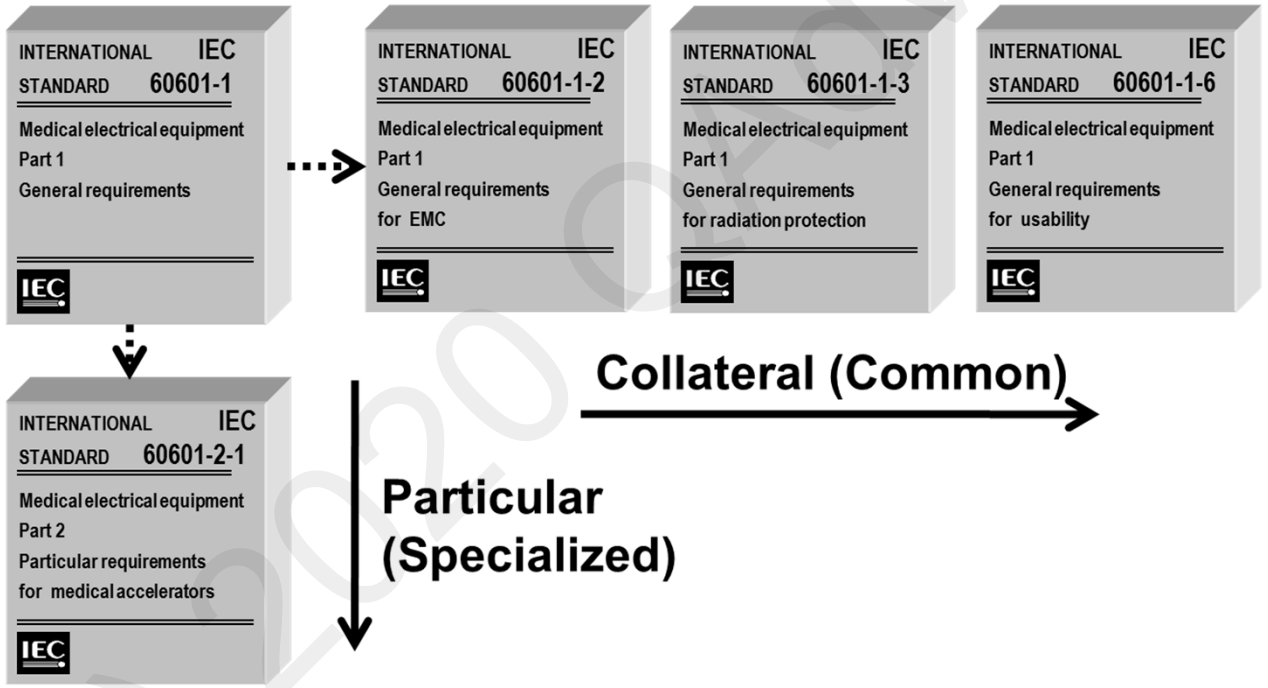
Collaterals and particulars…



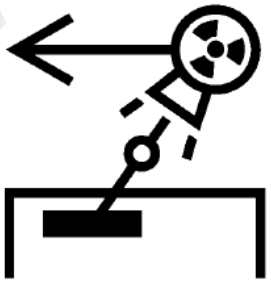
And some extras

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

5402



Tomographic movement with X radiation

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

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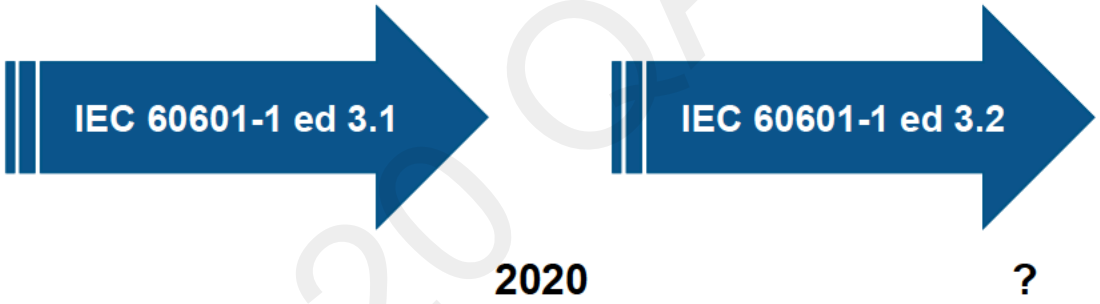
Transition times– the fine print



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The world outside EU

USA

- FDA Recognised consensus standards

China, Japan, Korea…

Check acceptability of

standards

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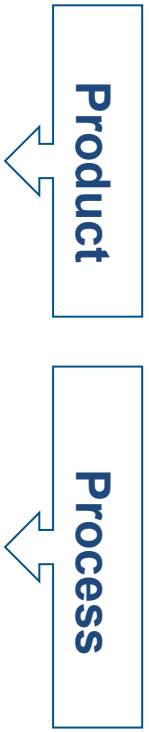
Example: Electromedical device for home use

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

- ISO 13485 Quality management system
- ISO 14971 Risk management
- ISO 10993 Biological evaluation
- IEC 62304 Software life cycle processes
- *IEC 80001-5-1 Security lifecycle processes*
- IEC 62366-1 Usability



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Example: In vitro diagnostic device

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

Product

- ISO 13485 Quality management system
- ISO 14971 Risk management
- IEC 62304 Software life cycle processes
- *IEC 80001-5-1 Security lifecycle processes*
- IEC 62366-1 Usability

Process

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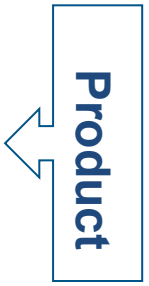
Example: SaMD (Software as a Medical Device)

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



- ISO 13485 Quality management system
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- IEC 62366-1 Usability

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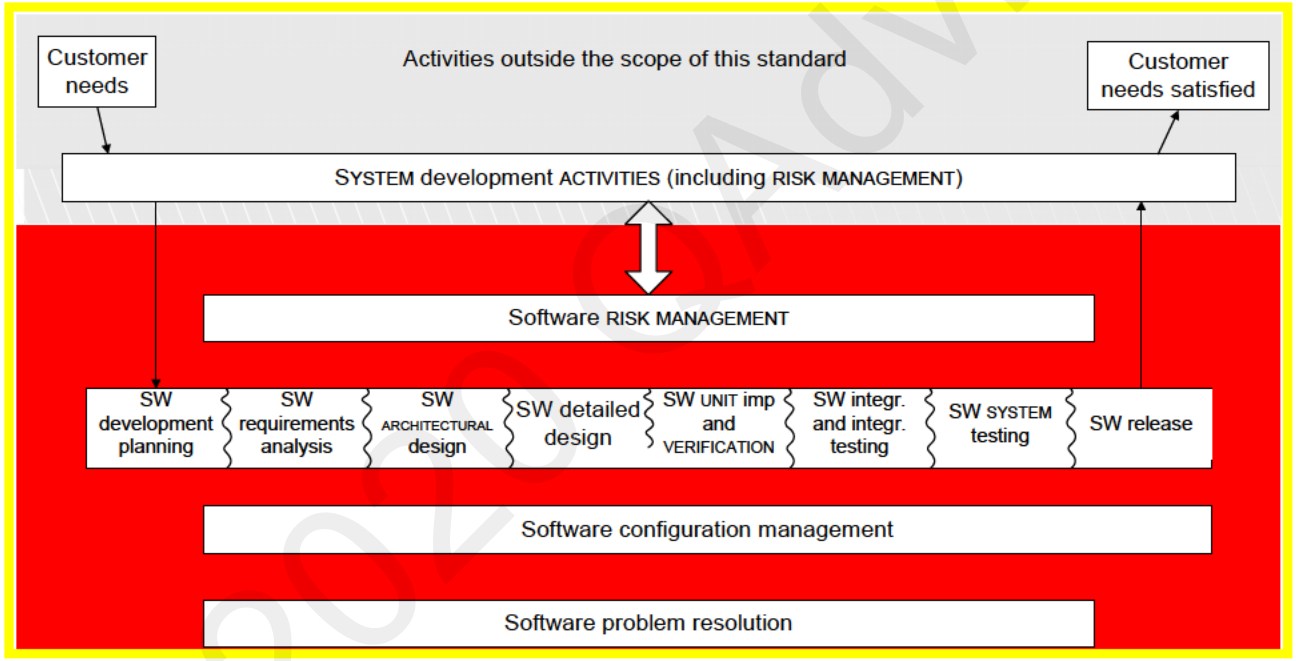
The structure of 62304 is aligned with system level standards, IEC 60601-1 or IEC 82304-1



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
Security lifecycle processes – IEC 80001-5-1
Biocompatibility - ISO 10993

Process

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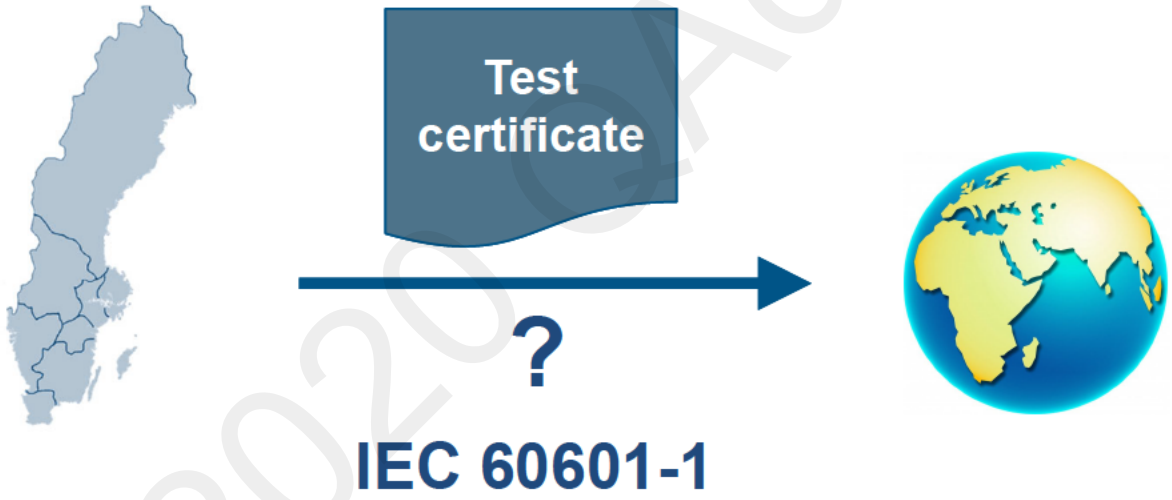
Test reports outside EU



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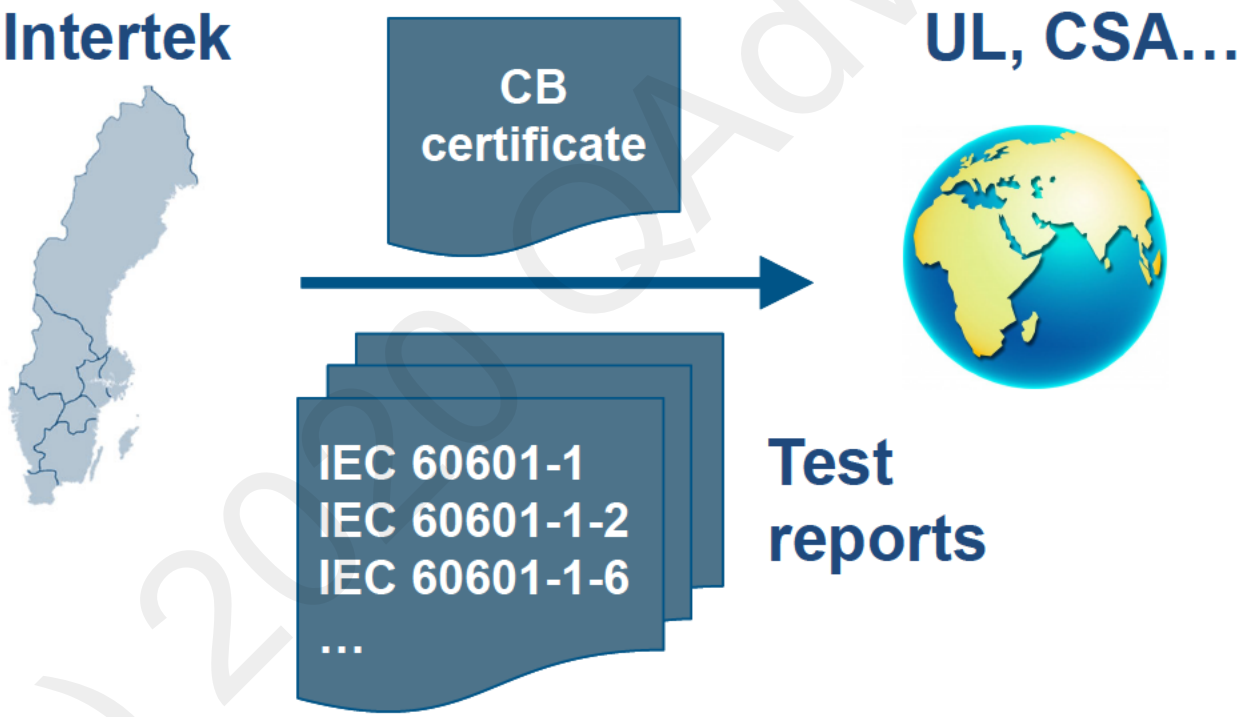
CB scheme – (IECEE System)



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QAdvis services

- **MDR transition support**
- **IVDR transition support**
- **CE marking support**
- **Risk management/Clinical evaluation**
- **Software validation**
- **Training**

Q&A

Questions you give “thumbs up” will automatically be prioritized up in the flow

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Short evaluation

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