Medical device SW – challenges in the EU

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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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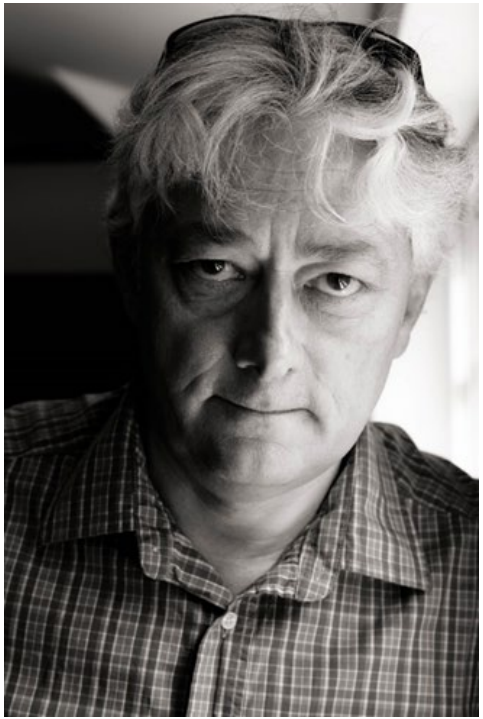
Presentation of the trainers - Robert Ginsberg



- 30+ years in SW Development
- 25+ years in Medical Device SW
- Participated in > 20 audits, FDA, MDD, etc.
- Certified Lead auditor (ISO 13485 & QSR)
- Co-author to IEC 62304, 82304-1, 80001-1, 80002-1, 80002-2
- Scrum Master
- SW Expert EU SW Workgroup & MDCG

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EU Regulations are changing

Medical device directives

AIMD, 90/385/EEC

MDD, 93/42/EEC

Lasted 24 and 27 years!

Transition has started
End date May 2020

Medical Device Regulation (MDR)

MDR 2017/745

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EU Regulations are changing

In-vitro diagnostic medical device directive

IVDD, 98/79/EC

Transition started
End date May 2022

In Vitro Diagnostic Device Regulation (IVDR)

IVDR 2017/746

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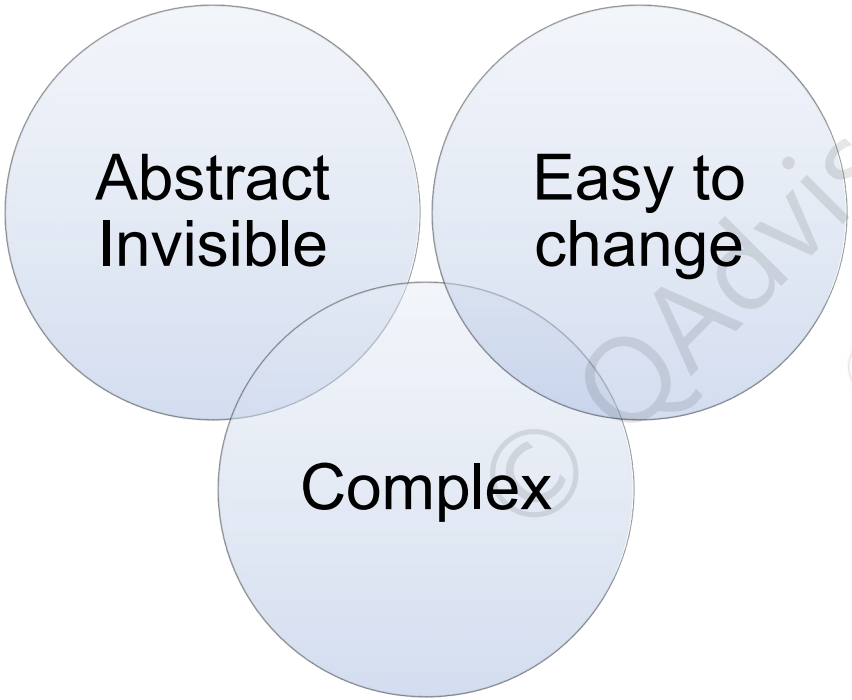
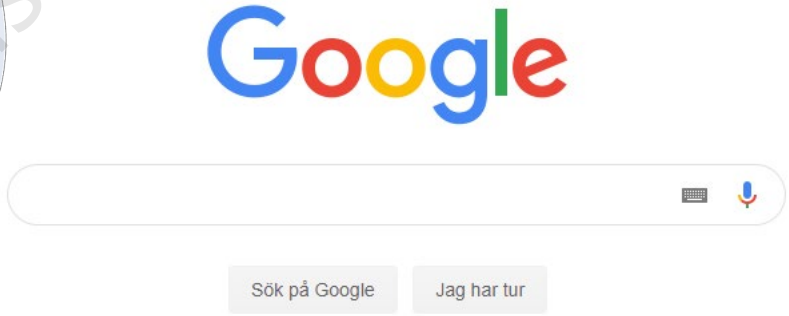
What makes software special?





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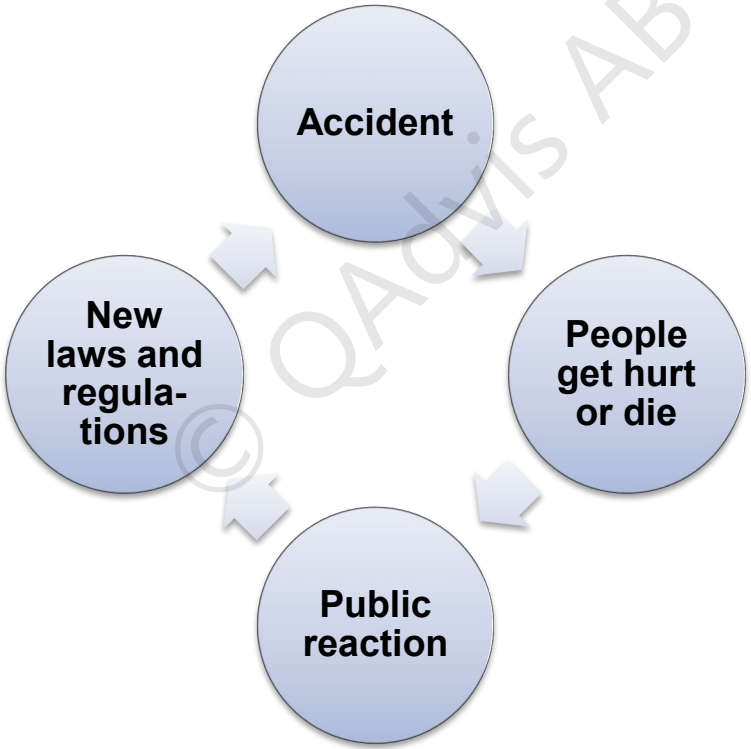
The bar is raised over time



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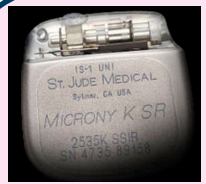
The MDR is much more demanding on software providing clinically relevant information

Case report: Socialstyrelsen 2007

”When Sofie came into ER, the treating doctor used the wrong patient e-record. In the computerized record system at the hospital there were two patients with similar names and social security numbers. Based on the contents of the wrong e-record Sofie was treated with drugs that led to her death.”

Swedish Socialstyrelsen = Swedish National Board of Health and Welfare

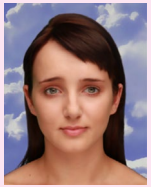
Medical device software can have many shapes



Embedded software SYSTEMS

Software as a Medical Device

Mobile apps



Web services

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New software technologies are quickly implemented in medical devices, for example AI

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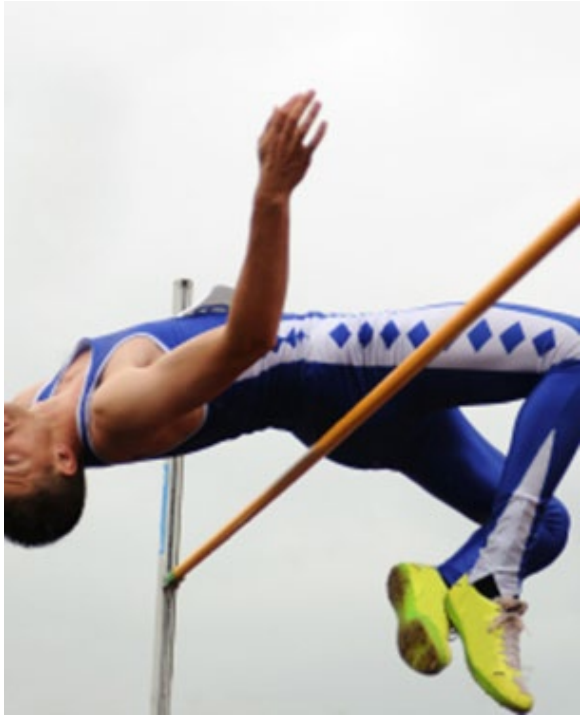
Medical Device Regulation (MDR) is raising the bar for medical device software

- General Safety and Performance Requirements
  - Information security
  - Single fault conditions
  - …
- Rule 11 - Many SaMD will be classified as IIa or higher
- Rule 22 – active therapeutic devices might end up in class III



SaMD = Software as Medical Device

GSPR of MDR will be much more demanding on MD SW, including SaMD

MDD	MDR	
12. Requirements for medical devices connected to or equipped with an energy source	**17. Electronic programmable systems - Devices that incorporate electronic programmable systems and software that are devices in themselves**	
12.1. Devices incorporating electronic programmable systems must be desi… perform… the eve… means … conseq…	17.1 Devices that incorporate electronic programmable systems, including	Similar
12.1a … softwar… the sta… develop…		
	features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).	
	17.4 The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.	New requirement

17.1 Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

GSPR = General Safety and Performance Requirements, SaMD = Software as a Medical Device

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There are guidelines on their way to interpret the expectations in MDR and IVDR for software

MEDDEV 2.1/6
Qualification and Classification of stand alone software

Guidance on Classification for SW in MDR and IVDR

Qualification of Device Software

Guidance on Clinical Evaluation of Medical Device SW

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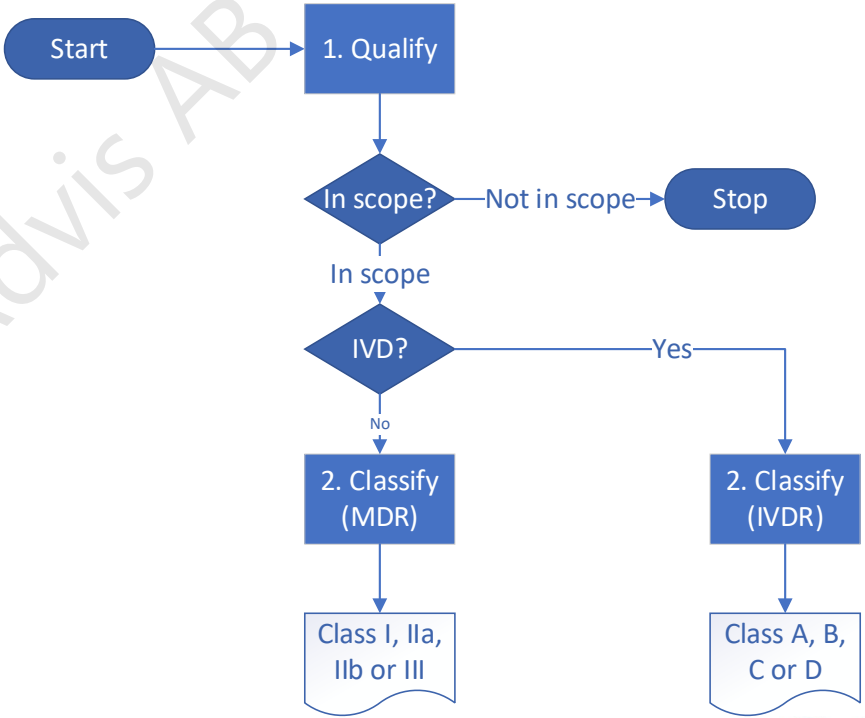
There are changes in qualification and classification of software



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Not in scope of a medical device

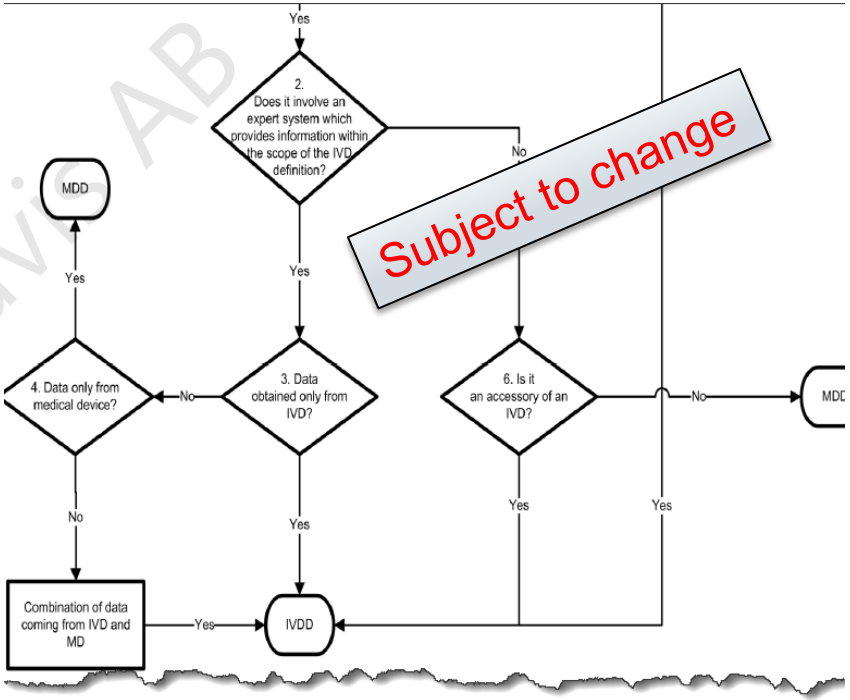
If your SW has a medical purpose, but is only intended to

- communicate
- store
- lossless compress
- perform a simple search

it is not considered as a medical device

There are upcoming changes in qualification of software, and your current IVD software might become a MD

- Is your software a medical device?
- Is your software a MD or IVD product?



MD = Medical Device, MEDDEV 2.1/6 - Qualification and Classification of stand alone software

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Intended Use is crucial for classification of SaMD. What is the class of a device tracking female ovulation?

SaMD = Software as a Medical Device

There is a new classification rule in MDR for active therapeutic devices – No. 22

- Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III

  New candidates in addition to external defibrillators:

  – Systems that control the temperature in baby incubators via skin sensors
  – Systems that regulate ultrafiltration in dialysis depending on the patient's blood pressure
  – Systems that automatically adjust ventilation patterns to the patient's condition

Source: https://www.tuv-sud.com

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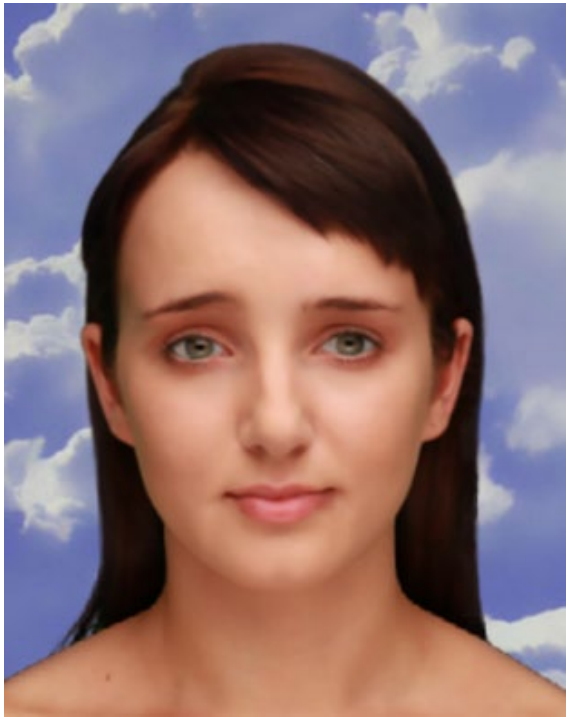
There is a new classification rule in MDR for medical device software – rule 11



- Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes - Class IIa
  - May cause death – Class III
  - May cause serious deterioration of state of health or surgical intervention – Class IIb
- Monitoring of physiological processes – Class IIa
- Monitoring of vital physiological parameters, variations of those parameters could result in immediate danger – Class IIb
- All other software – Class I

For complete wording, see Annex VIII of MDR

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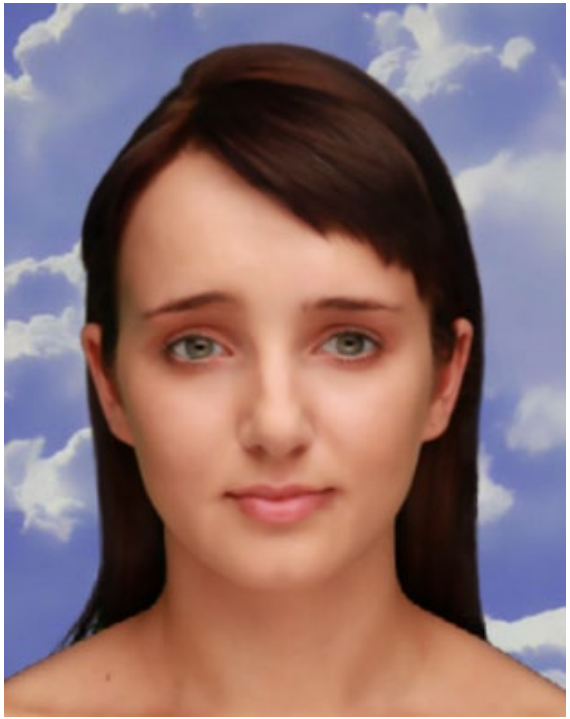
There is a new classification rule in MDR for medical device software – rule 11



If the software provides clinical information:

Class IIa or higher

A very simplified view. For complete wording, see Annex VIII of MDR

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You must consider rule 11 having a software based medical device under MDR

MDR SW

Provides information for medical purpose

Rule 11

Software that provides information for medical purposes where that information is intended on its own to result in driving or influencing the use of a (hardware) medical device

Exclusively drives or influences the use of a device

(Implementing rule 3.3 only)

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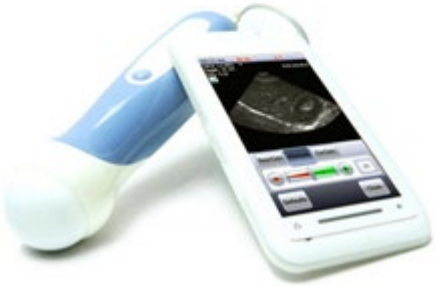
There are two aspects to consider classifying software

- Is your software driving or influencing the use of a medical device? - IIa
- Is your software providing information for diagnostic or therapeutic purpose? - III



Mobile phone based ultrasound system ➔ Class III

Rule 11 is sometimes compared with a slippery slope

- Rule 11 is severity based
  - Significant risk that a lot of software ends up in class III
- Guidance documents not published
  - End of the year – maybe?
- MDR is a challenge for NBs
  - Will they challenge rule 11?

Be prepared for an overshoot of ambition level for software based products

IMDRF schema might be supportive interpreting rule 11

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	III	IIb	IIa
Serious	IIb	IIa	IIa
Non-serious	IIa	IIa	IIa

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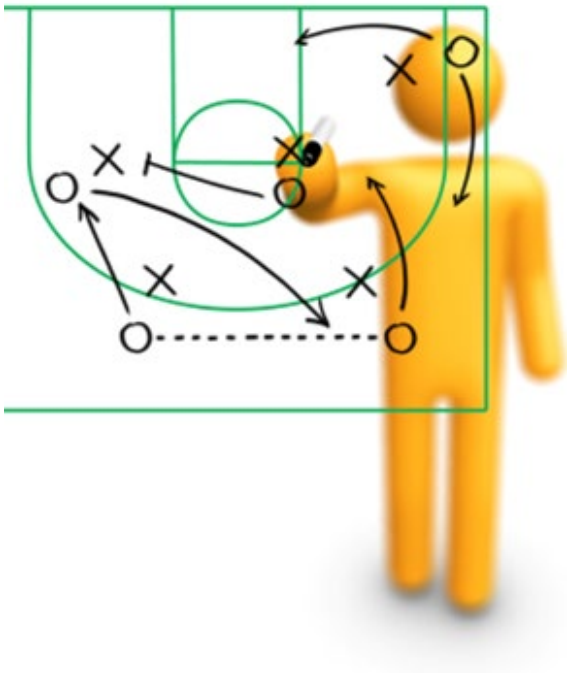
There is a new classification rule in MDR that has a large implication on medical device software



- Many SW based products will get a classification of Class IIa or higher
- Need of a Notified Body for class IIa or higher
  - Certified Quality Management System
  - External review of technical documentation
- Potential implications are not fully explored

SaMD = Software as a Medical Device

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In Vitro Diagnostics Regulation (IVDR)

- Many SaMD will get a classification of class B or higher
- Need of a Notified Body
- Some might turn out as MDR devices
- No transition time for Class General (IVDD)

Warning for confusion between IVDR classification A/B/C/D and Software Safety Classification A/B/C in IEC 62304

SaMD = Software as a Medical Device

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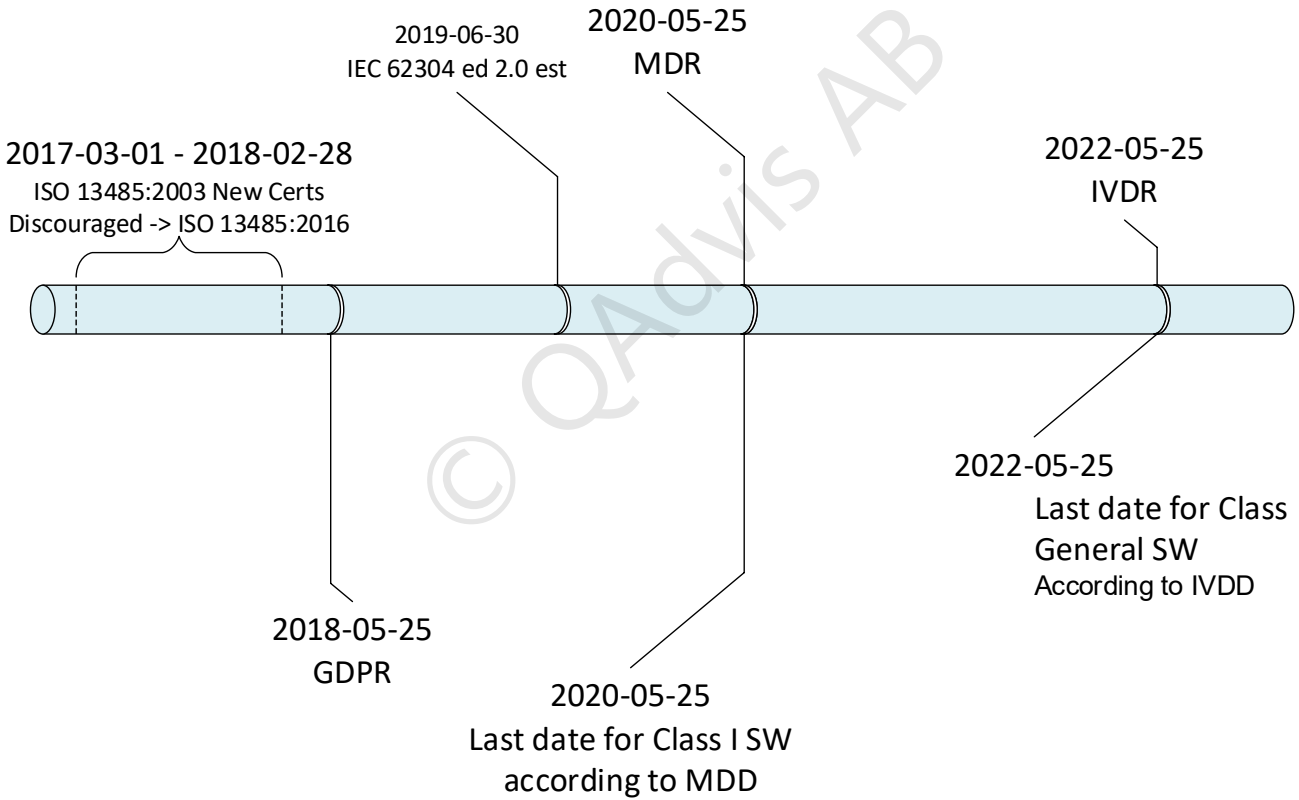
Software related timelines are tight for many companies



Summary of implications for medical device software companies

- No transition time for class I
- More companies will be scrutinized by Notified Bodies
- Risk of bottlenecks (Notified Bodies, …)
- It will take time to sort out details in interpretation of the new regulations
- Challenging General Safety and Performance Requirements (GSPR)

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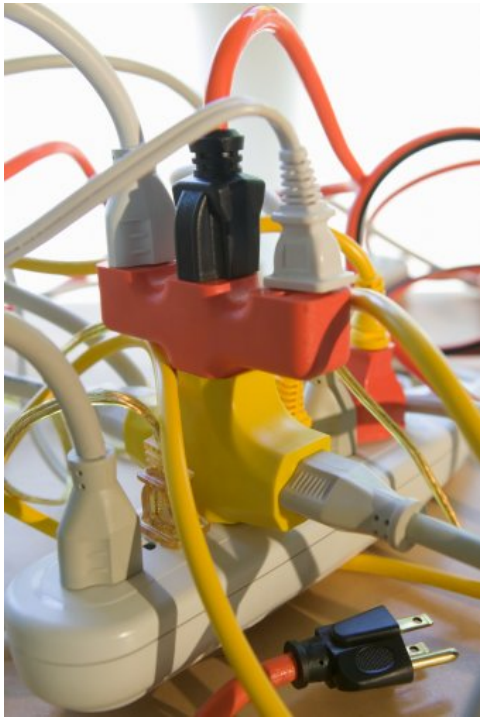
Status on harmonization and MDR



- Things go a little bit slow …
- No new harmonized standards under the MDD from IEC.
- For MDR a few will be done to 2020 and only slightly more to 2024

Use state-of-the-art standards in consultation with your NB

MDR = Medical Device Regulation 2017/745, NB = Notified Body

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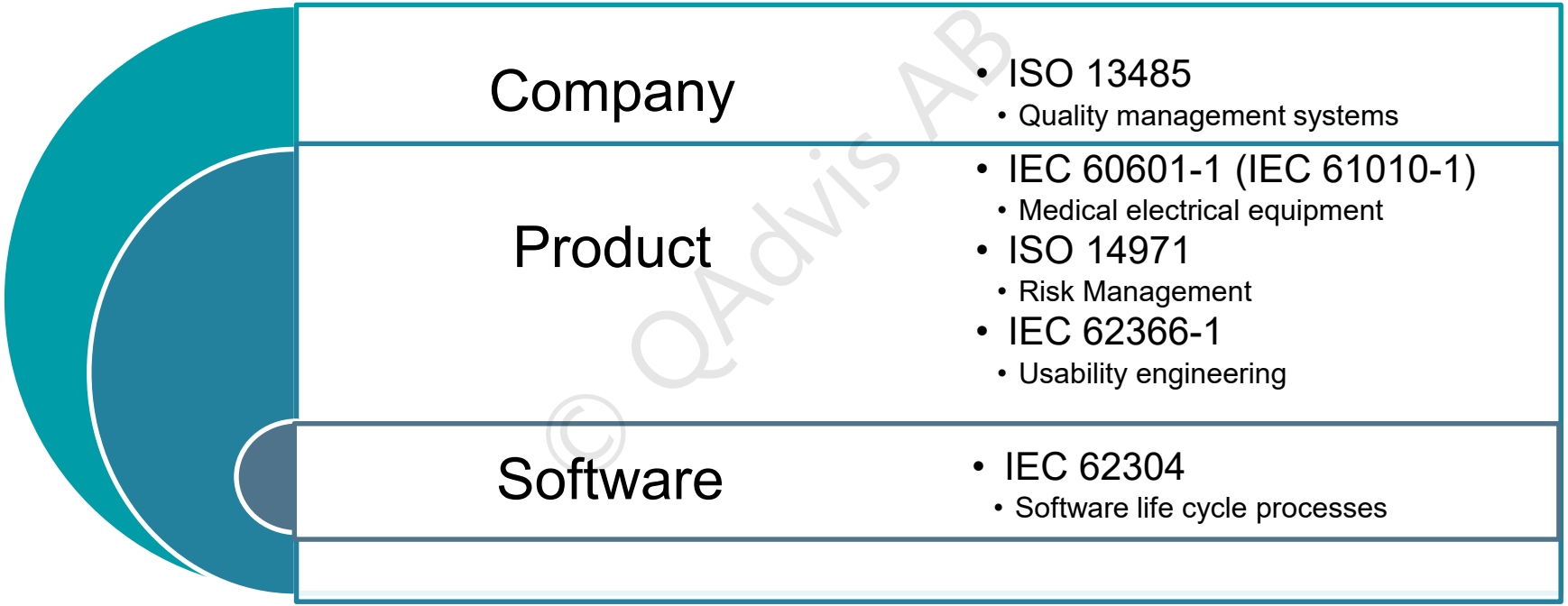
Relevant standards for Medical Devices containing SW according to MDR/IVDR



A similar image can be drawn for IVDD/IVDR

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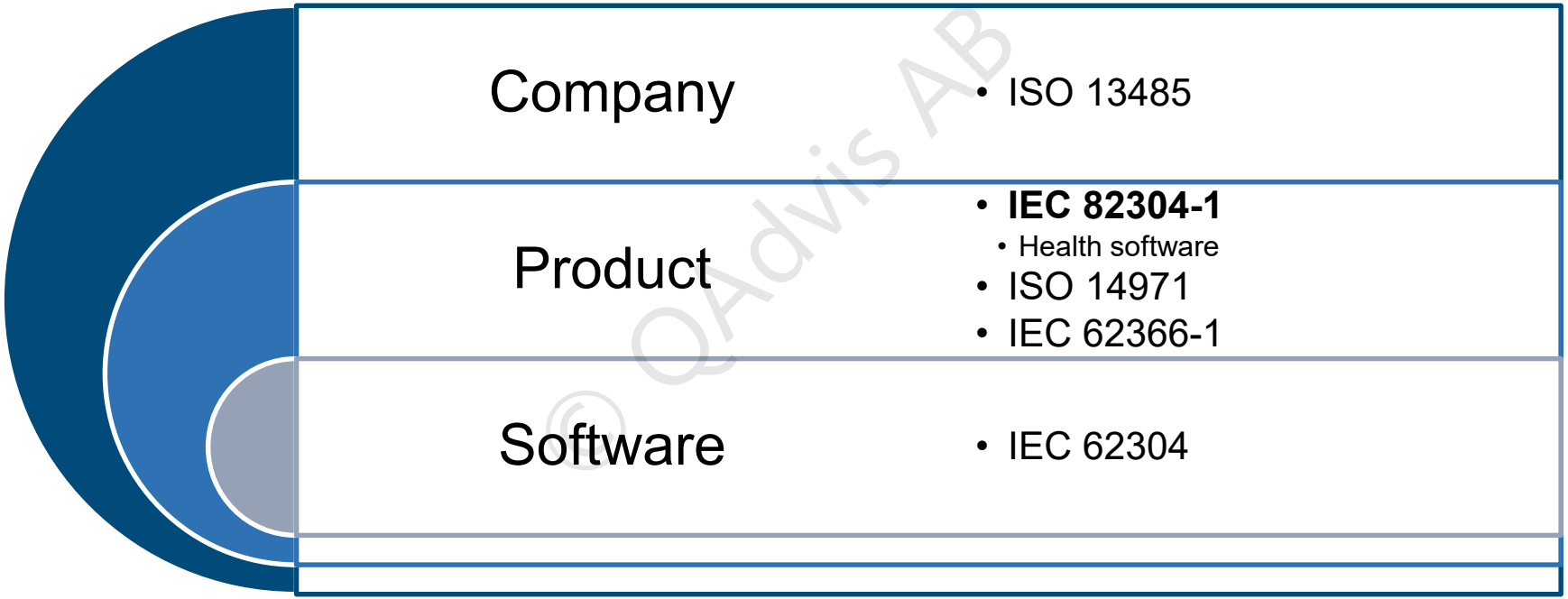
Relevant standards for Software as a Medical Device (SaMD) according to MDR/IVDR



IEC 82304-1: Health Software – Part 1: General requirements for product safety

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IEC 62304 ed 2.0 is assumed to be published next year

- Scope extension - will include Health Software
- Higher expectations on risk management of cybersecurity aspects
- Very useful informative annexes

Health software - software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Summary and recommendations - MDR transition

- Don’t wait for clarifications – act now – the clock is ticking!
- Make a migration plan, get management buy in, secure resources and budget
- Assess your qualification and classification
- Stand in line for a NB – if needed
- Follow the standards for SW (state of the art)
- Use IMDRF documents when in doubt
- Rework your migration plan periodically having new information
- Gather product performance data to make the transition to MDR/IVDR easier

“You don’t have to run faster than the bear to get away. You just have to run faster than the guy next to you.”
- Jim Butcher

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Q&A

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QAdvis services

- Regulatory advice
- Implementation of QMS
- Development of product documentation
- Risk management/Clinical evaluation
- Software validation
- Training
- Implementation of tools

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