Rule 11 in MDR – practical considerations

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Your Regulatory Partner

sis STANDARD DEVELOPER 2019

SEK SVENSK ELSTANDARD

EAAR European Association of Authorised Representatives

SWEDISH Medtech

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There is a new classification rule in MDR for medical device software – No. 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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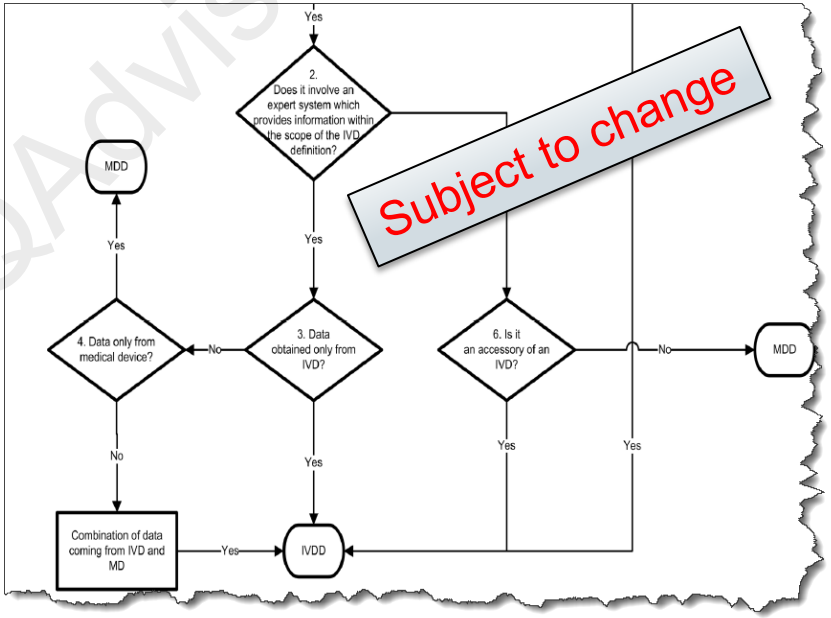
There are upcoming changes in qualification of software, and your current IVD software might become a MD

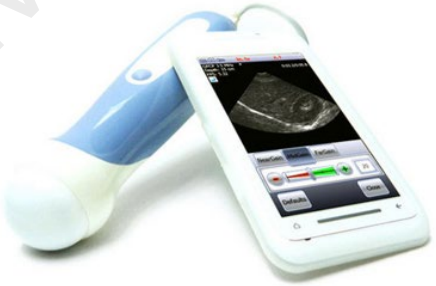
- Is your software a medical device?
- Is your software a MD or IVD product?



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

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?

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 designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	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.	Similar Requirement completed for clarity Partial change
12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	17.2 For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	Partial change
	17.3 Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific 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).	New requirement
	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

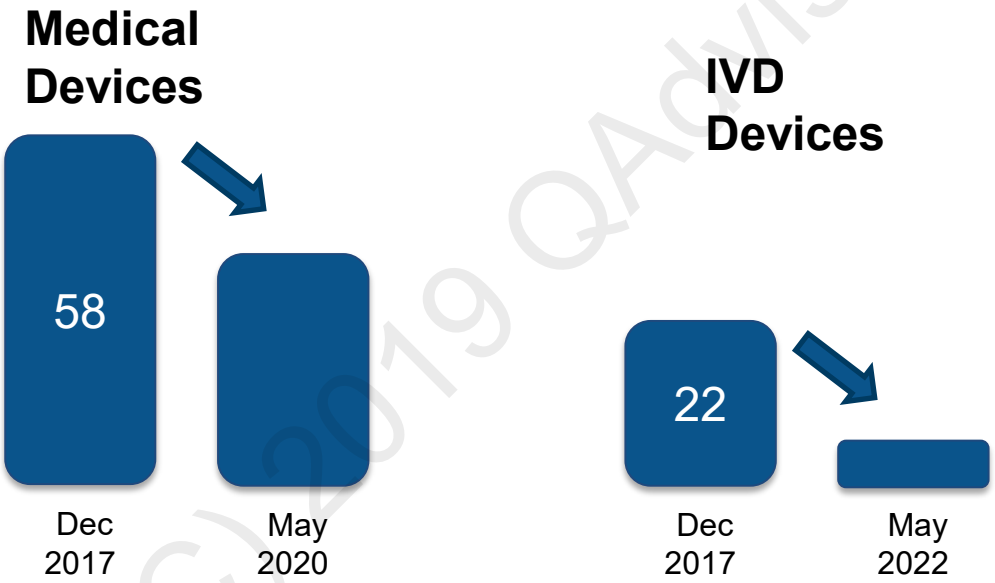
GSPR = General Safety and Performance Requirements, SaMD = Software as a Medical Device

Need to be aware - and to act

- Strategy for current product portfolio - regulatory aspects
- Strategy for future product portfolio – regulatory aspects

Time is limited!

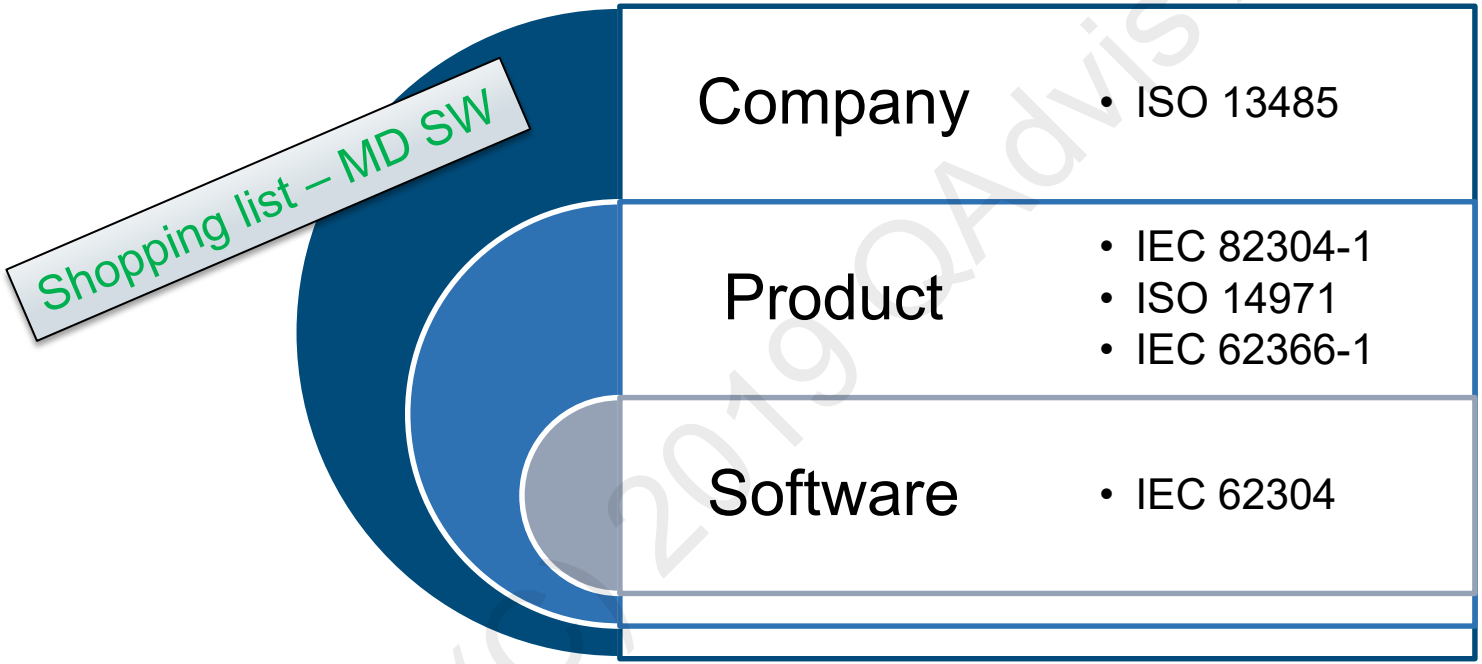
Notified Bodies – Get one now!



Address hot topics for software where the expectations are increased

- Software risk management
- Cybersecurity
- Usability

Stick to the standards even if the harmonization process is slow



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

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 IMRDF 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

Q&A

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

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
- SW Expert EU SW Workgroup & MDCG
- Scrum Master

QAdvis services - software

- **Implementation of QMS**
- **Development of product documentation**
  - **IEC 82304-1**
  - **IEC 62304**
- **Risk management**
- **Clinical evaluation**
- **Implementation of tools**
  - **IEC/TR 80002-2**
- **Training**