Your Regulatory Partner

Guidance on Qualification and Classification
of Software in Regulation (EU) 2017/745 – MDR
and Regulation (EU) 2017/746 – IVDR
A short introduction – 2019-10-14

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Please note that, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts.

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 author - Robert Ginsberg

- 30+ years in SW Development
- 25+ years in Medical Device SW
- Participated in numerous 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 observer
- Scrum Master

Agenda

1	Intro to regulations and background
2	MD Software in EU
3	Wrap up and Q&A

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1	**Intro to regulations and background**
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EU Regulations are changing for Medical Devices

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 - Medical Device Regulation (MDR)

- All current CE-marked devices need to be re-CE marked to survive 2020 + (4years for class Im, Is and higher)
- All new devices must meet MDR after May 2020 to be CE marked
- No transition time for class I devices

There is no "grandfathering" - <u>at all!</u>

EU Regulations are changing for In Vitro Medical devices

In-vitro diagnostic medical device directive

IVDD, 98/79/EC

Transition started
End date May 2022

In Vitro Diagnostic Device Regulation (IVDR)

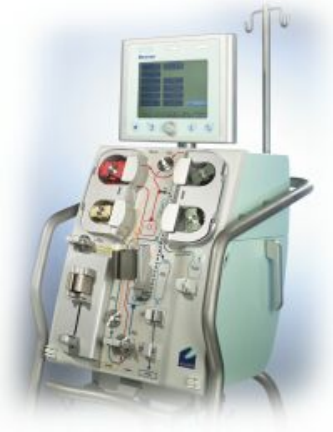
IVDR 2017/746

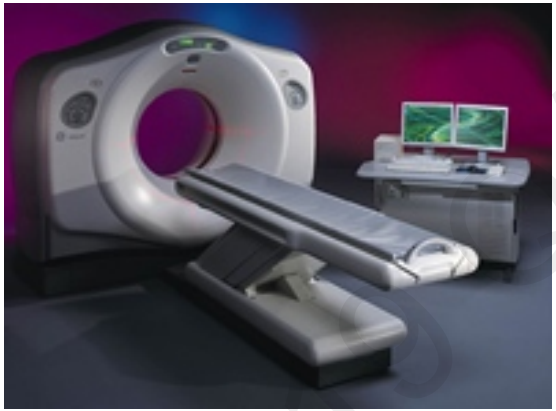
EU - In Vitro Diagnostic Regulation (IVDR)

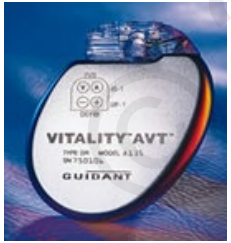
- Many MDSW products will get a classification of Class B or higher
- Need of a Notified Body
- No transition time for Class General products

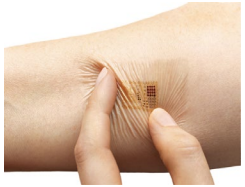
MDSW = Medical Device software

What is Medical Device software in the EU?









The Medical Device definition is crucial qualifying a software to be a Medical Device

'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

(MDR/IVDR Article 2 (1))

Medical Device - definition

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

(MDR/IVDR Article 2 (1))

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

- Contra-conception – Class IIb
- Pro-conception – Class I
- Otherwise – maybe not a medical device at all?

MDSW = Medical Device software

MDR classification, there are several changes for software based medical devices

Examples:

- Rule 11 – new rule
  Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes
  – Class I, IIa, IIb or III

- Rule 22 – new rule
  Active therapeutic devices with integrated diagnostic function
  – Class III

Clinical Evaluation is also needed for Medical Device software

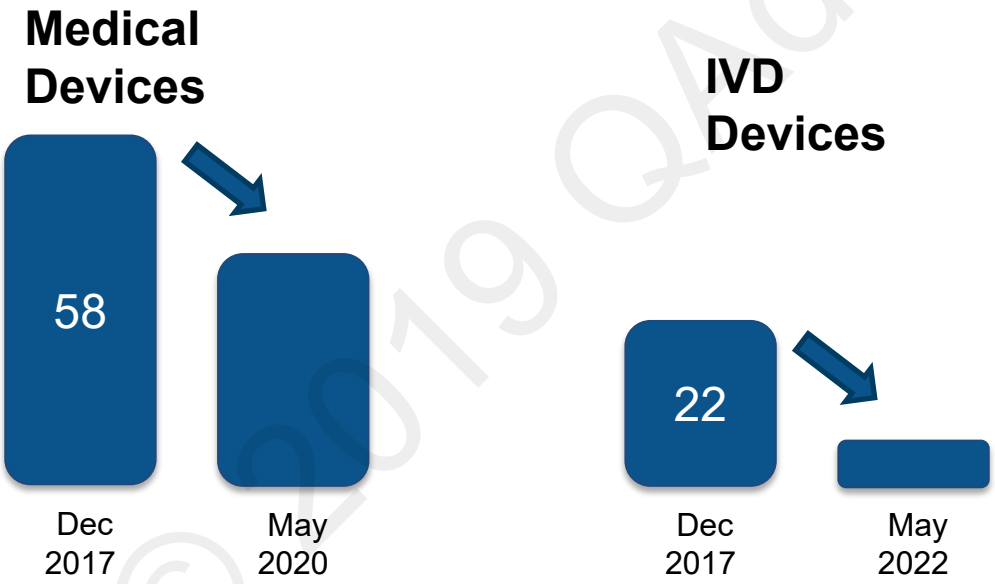
- Update Clinical Evaluation reports
- Need sufficient clinical data
- Claim equivalence with other products much more difficult

Conclusion: More clinical data may be needed. PMCF may be initiated (now!) for “re-CE marking”. (Portfolio strategy)

A guidance document will be soon released

PMCF = Post-Market Clinical Follow-up

Notified Bodies – Dropouts and limited scope are a significant challenge for the EU system



You need to be aware and act now

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

Time is limited!

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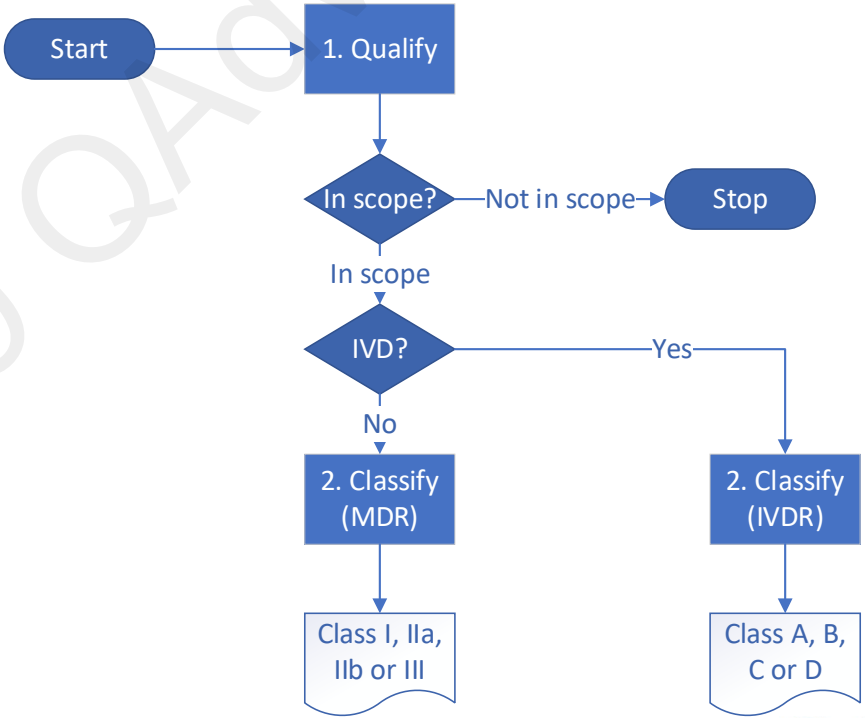
Be aware of differences in terminology

EU guidance	Software standards IEC 62304 and IEC 82304-1
Medical Device Software (MDSW) Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation in vitro diagnostic medical devices regulation.	**Medical Device Software** Software System that has been developed for the purpose of being incorporated into the Medical Device being developed or that is intended for use as a Medical Device.
-	**Health Software** Software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

There are changes in qualification and classification of software



There are exemptions to qualification of software as a Medical Device

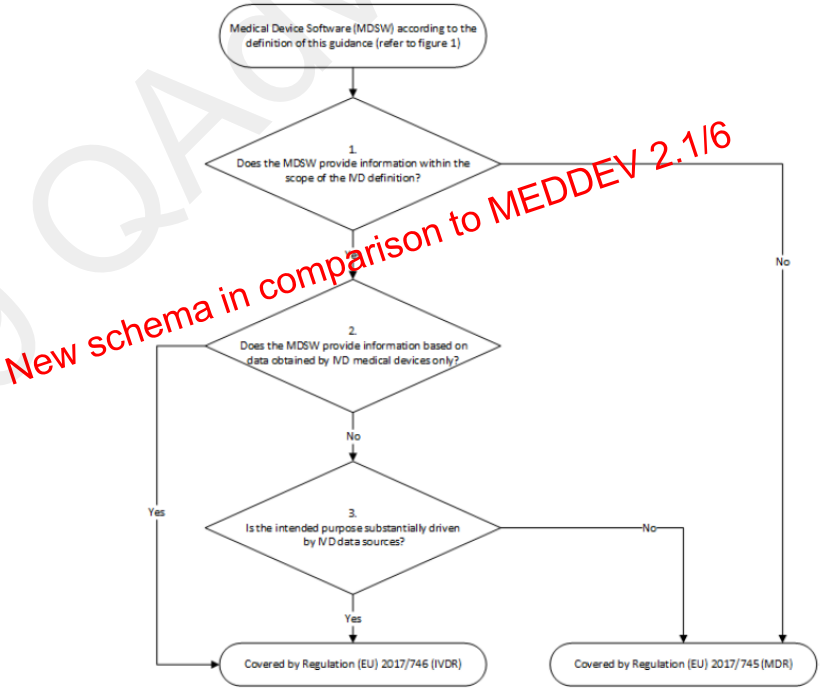
If your SW has a medical purpose, but is only intended to

- store
- archive
- communicate
- perform a simple search

it is not considered as a medical device

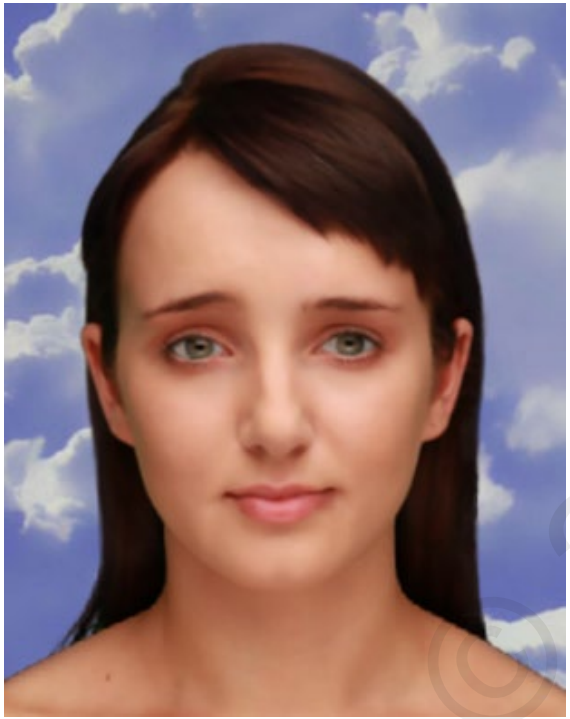
There are upcoming changes in qualification of software, and your current IVD software might become a MD

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



MD = Medical Device

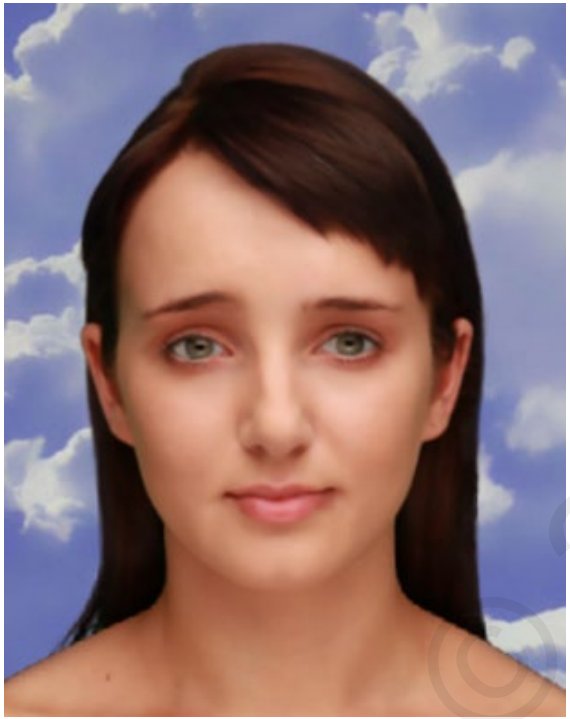
There is a new classification rule in MDR for medical device software – rule 11



- 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

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

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 is a new classification rule in MDR for active therapeutic devices – rule 22

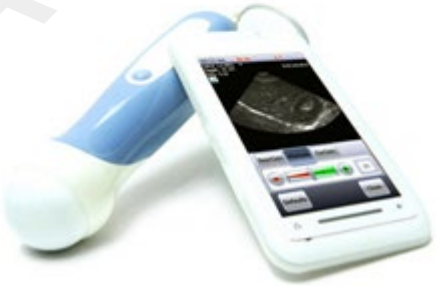
- Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III

  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 based on feedback from a physiological parameter

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

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

A simplified view – the classification is dependent on the Intended Use

Rule 11 is sometimes compared with a slippery slope

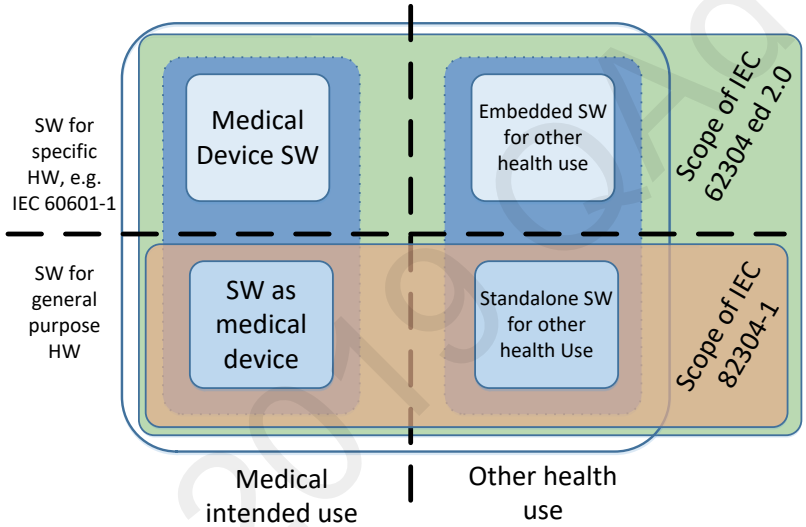
Rule 11 is severity based (no risk)

IMRDF schema will 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

IMDRF/SaMD WG/N12FINAL:2014

The scope of IEC 82304-1 (and IEC 62304 ed 2) is intended to also cover Health SW, which is a broader term in comparison to the Medical Device definition



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

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Conclusions

- A lot of work – start now!
- No grandfathering:

  Not ready in time = products can not be placed on the market
- Stricter requirements on all players (Authorities, Notified Bodies and Manufacturers)
- Sufficient clinical data necessary
- Many products will be up-classified

Suggested strategies moving forward

- Don’t wait with the transition to MDR or IVDR
- Make a migration plan, get management buy in, secure resources and budget
- Assess your classification
- Identify and address competence gaps in your company
- Stand in line for a NB
- Do a thorough product and SW risk management
  - SW “reliability”
  - Usability
  - Cybersecurity
- Follow the standards (state of the art)
- Use IMDRF documents when in doubt
- Rework your Clinical Evaluations (also for MDSW)
- Rework your migration plan periodically having new information
- Gather product data to simplify the transition to MDR/IVDR

MDSW = Medical Device software

QAdvis services for Medical Device software

- **Implementation of QMS**
- **Development of product documentation**
- **Usability**
- **Cybersecurity**
- **Software risk management**
- **Clinical evaluation**
- **Software validation**
- **Training**
- **Implementation of tools**

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MDCG guidelines

- MDCG 2018/2019 UDI guidance documents
- MDCG 2019-7 guidance person responsible for regulatory compliance
- MDCG 2019-8 Implant card
- MDCG 2019-3 Interpretation on article 54(2)b
- MDCG 2019-4/5 Eudamed registration
- MDCG 2019-11 Guidance on Qualification and Classification of Software
- …

(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en)

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