Your Regulatory Partner

Short intro to the MDR & IVDR

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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

Training/courses

CE-marking, MDR
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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Major changes for **medical device** and **IVD device** industry

- EU regulations
- Non-EU regulations
- Standards
- Brexit

Affecting all stakeholders: manufactuers, distributors, competent authorities, notified bodies, and many more

At the same time!

EU Regulations

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

EU Regulations

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 - Medical Device Regulation 2017/745 (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" - at all!

Notified Bodies

All Notified Bodies lose accreditation for MDD, in May 2020

Need to apply for designation for MDR

Need to be aware - and to act

Strategy for current product portfolio - regulatory aspects

Strategy for future product portfolio – regulatory aspects

Time is limited!

MDR is very dense with information

Takes time to read, digest and understand

No consensus on interpretation

EU - Medical Device Regulation 2017/745 (MDR)

Some important aspects

⇒ New classification assessment

⇒ New conformity routes to meet

⇒ New Essential Requirements (General Safety Performance Requirements)

⇒ Much stricter requirements for Clinical data

⇒ New labelling requirements, UDI (Unique Device Identification)

⇒ Much stricter classification for Software as a Medical Device

MDR classification, several changes

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 19 – new rule

Incorporating nanomaterial

– Class IIa, IIb or III

There is a new classification rule in MDR for SaMD – No. 11

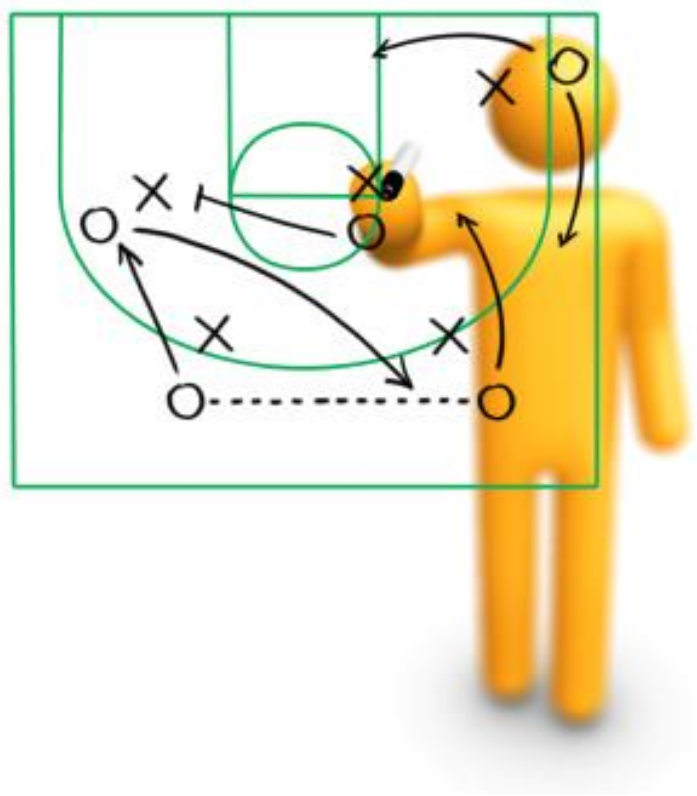
Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes – **Class IIa**

- May cause death – **Class III**
- May cause serious detoriation 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**

SaMD = Software as a Medical Device

(For complete wording, see Annex VIII of MDR)

There is new classification rule in MDR
Annex VIII, Chapter III, Rule 11



Many SaMD will get a classification of Class IIa or higher based on this rule

Need of a Notified Body for class IIa or higher
- -Certified Quality Management System
- -External review of technical documentation

Interpretation issues not resolved so far

Potential implications are not fully explored

In opposite direction to USA and 21st Century Cures Act for mobile devices

SaMD = Software as a Medical Device

Clinical evaluation

- 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)

PMCF = Post-Market Clinical Follow-up

EU - Medical Device Regulation 2017/745 (MDR)

Some important distribution/import aspects

⇒ New requirements for distributors to verify compliance of products, report

⇒ New requirements for importers to verify compliance of products

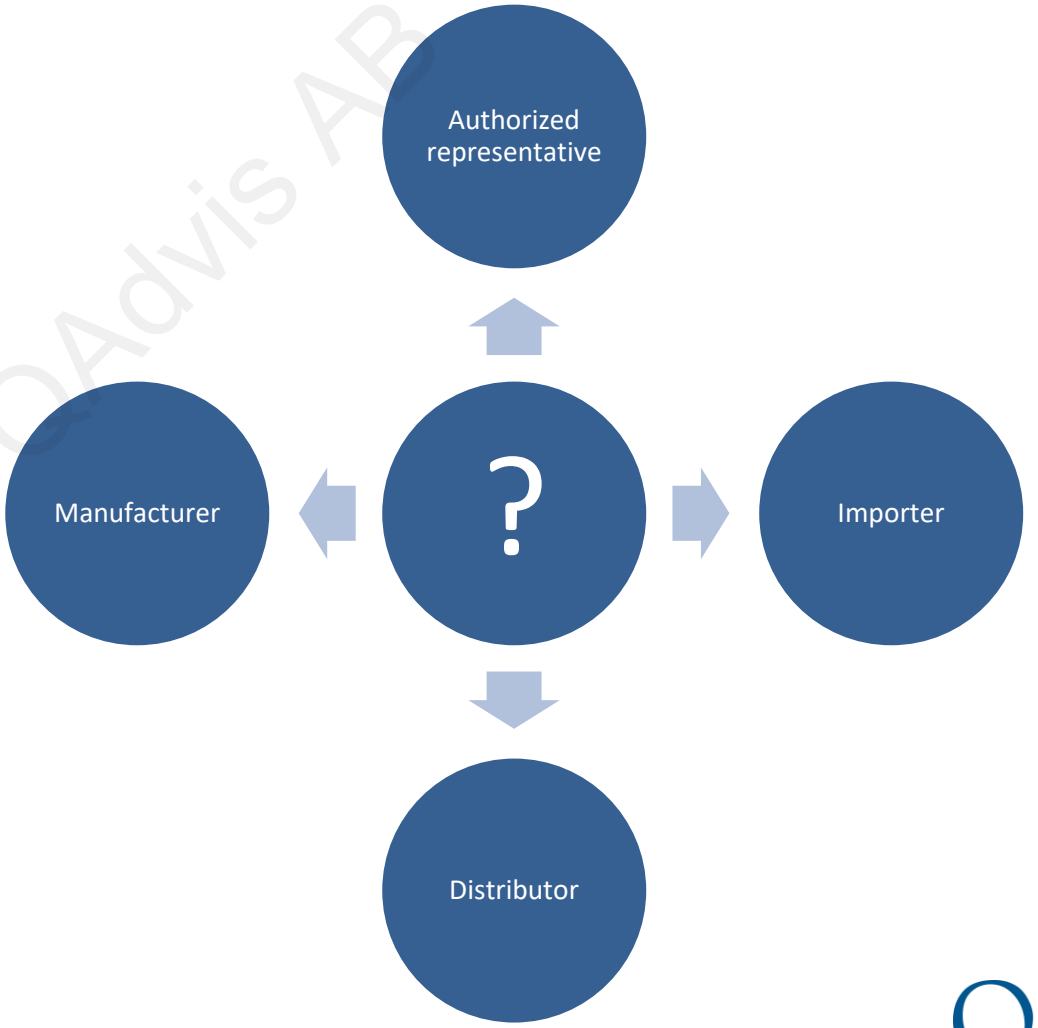
⇒ New requirements for authorized representatives to verify compliance of products

Who is responsible for what?

Your QMS must handle it all

Quality contracts with distributors, suppliers, auth rep, importer, etc.

Eudamed database!



Quality Management System (QMS)

- QMS compliance and integrity shall be maintained during changes
- MDR, IVDR transition plan needed
- QMS must handle both MDD and MDR requirements during next 3-5 years.

- ISO 13485:2016 entering its last transition year. March 2019

CEN/TR 17223:2018, relationship between 13485 v.s. MDR & IVDR

Prepare your company for the deadlines

Analyze and form your
MDR or IVDR strategy

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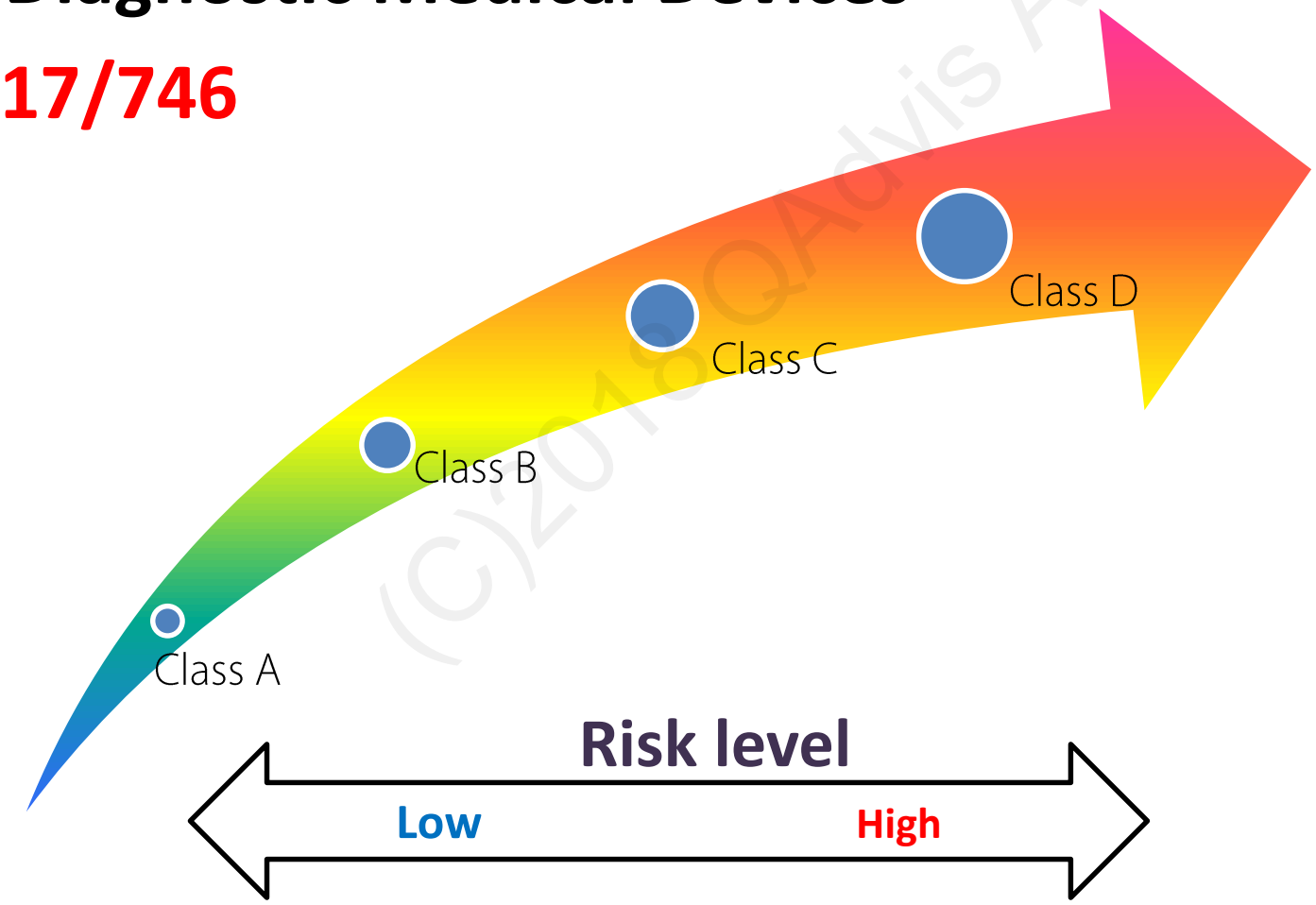
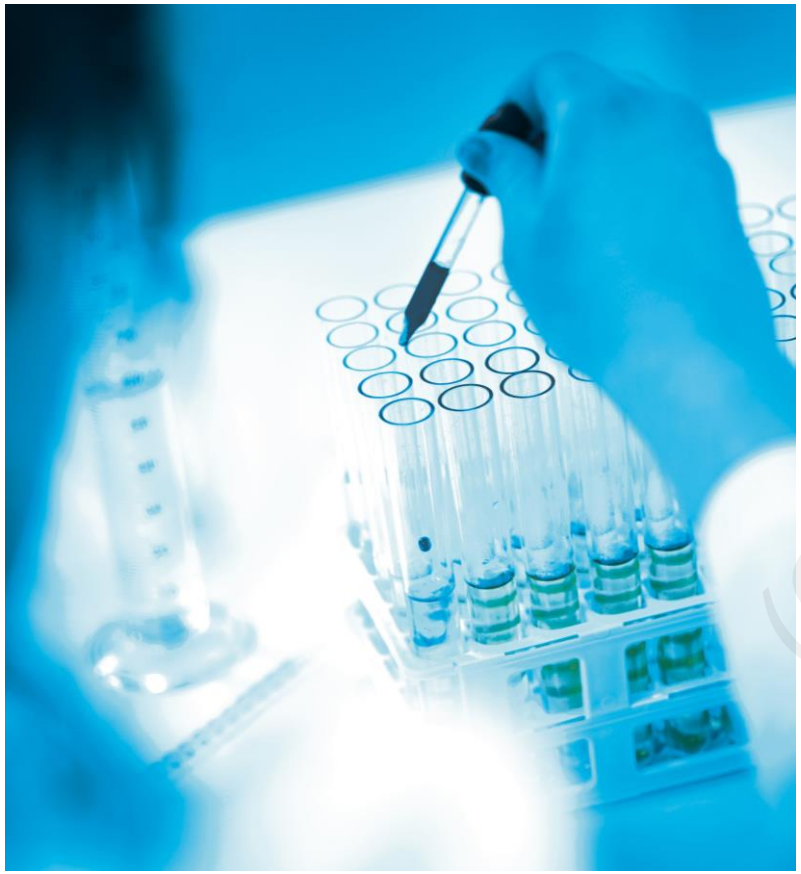
The classification scheme is based on patient risk

In Vitro Diagnostic Medical Devices

IVDR 2017/746



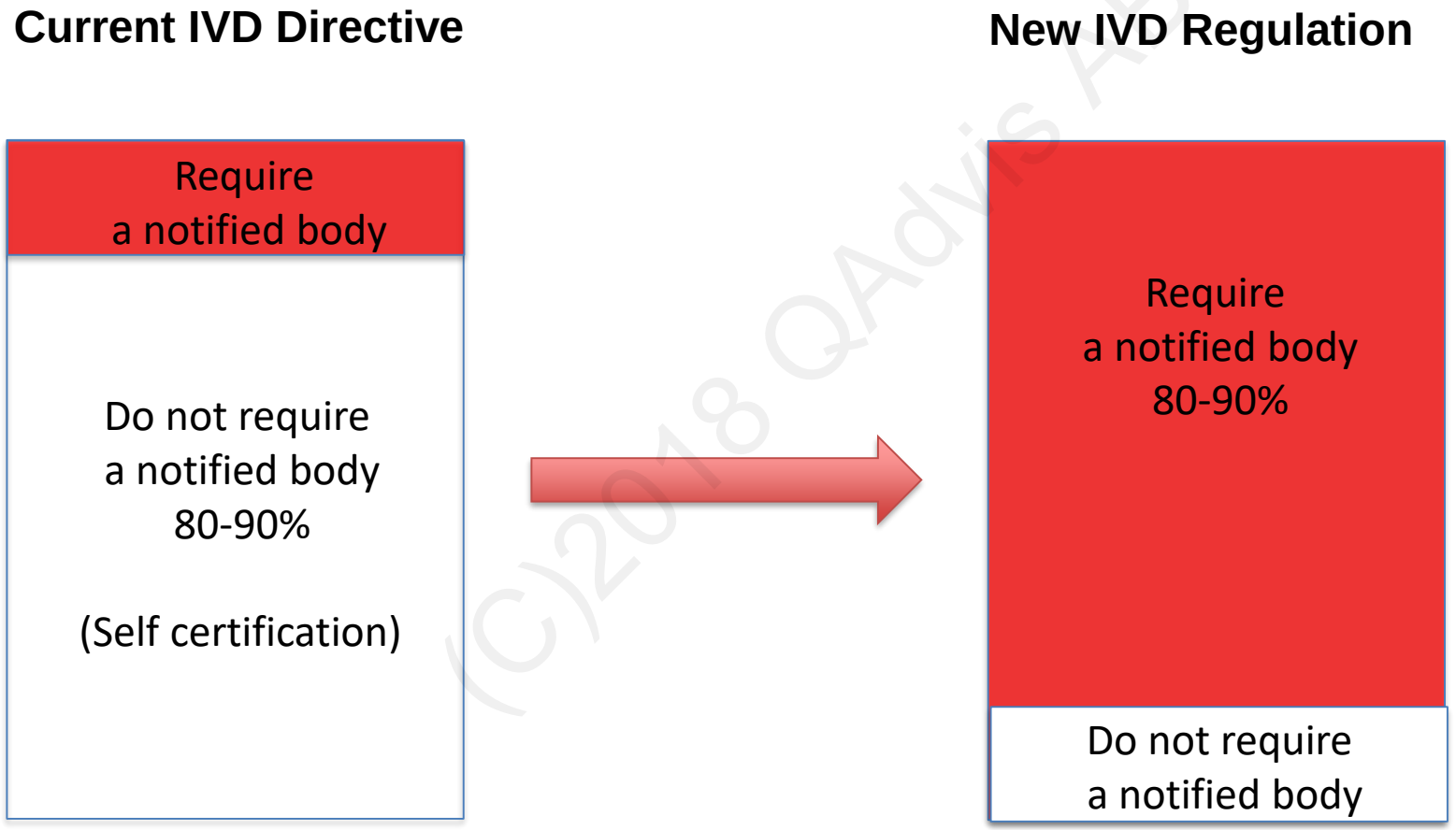
In Vitro Diagnostics Regulation (IVDR)



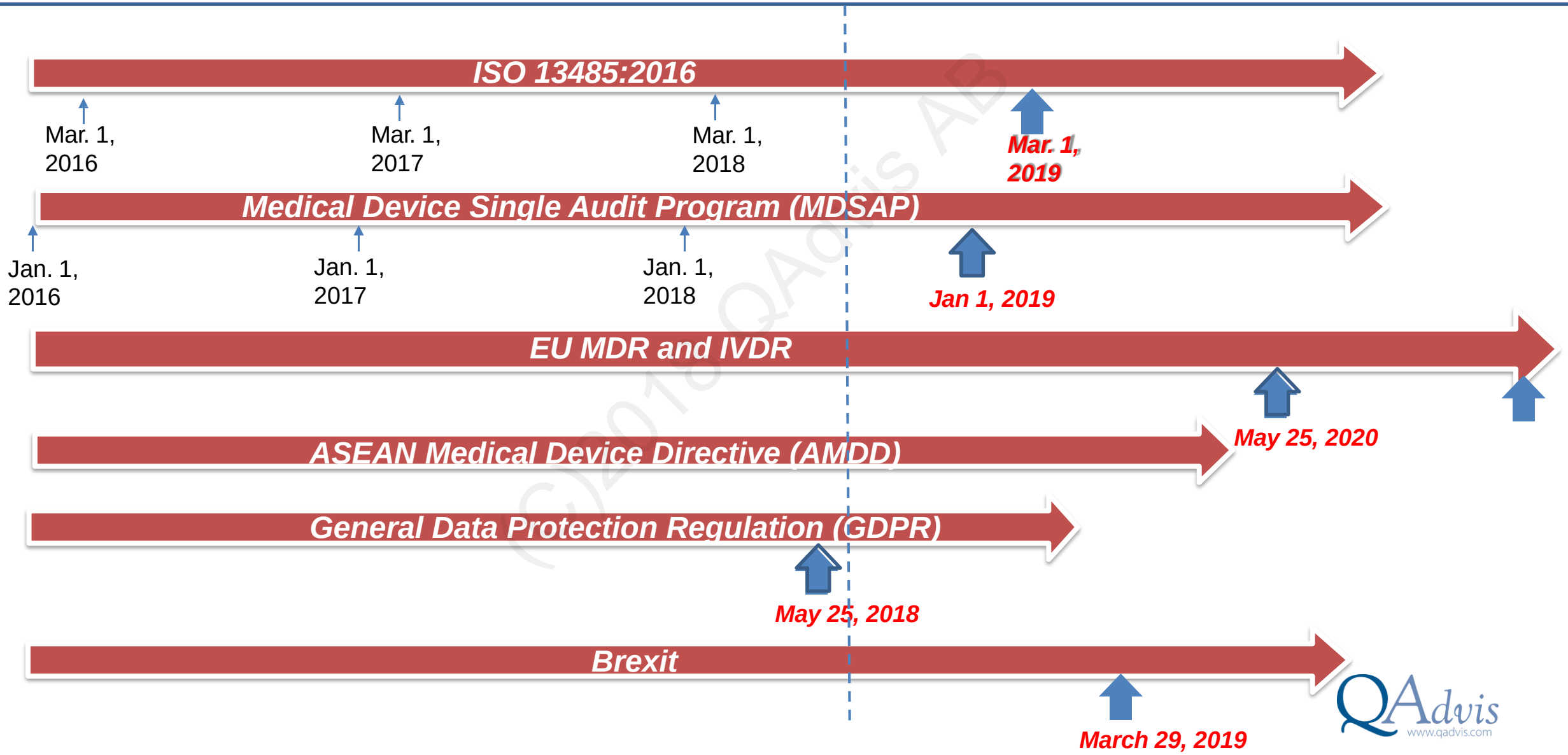
- Many SaMD will get a classification of Class B or higher
- Need of a Notified Body
- No transition time for Class General

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

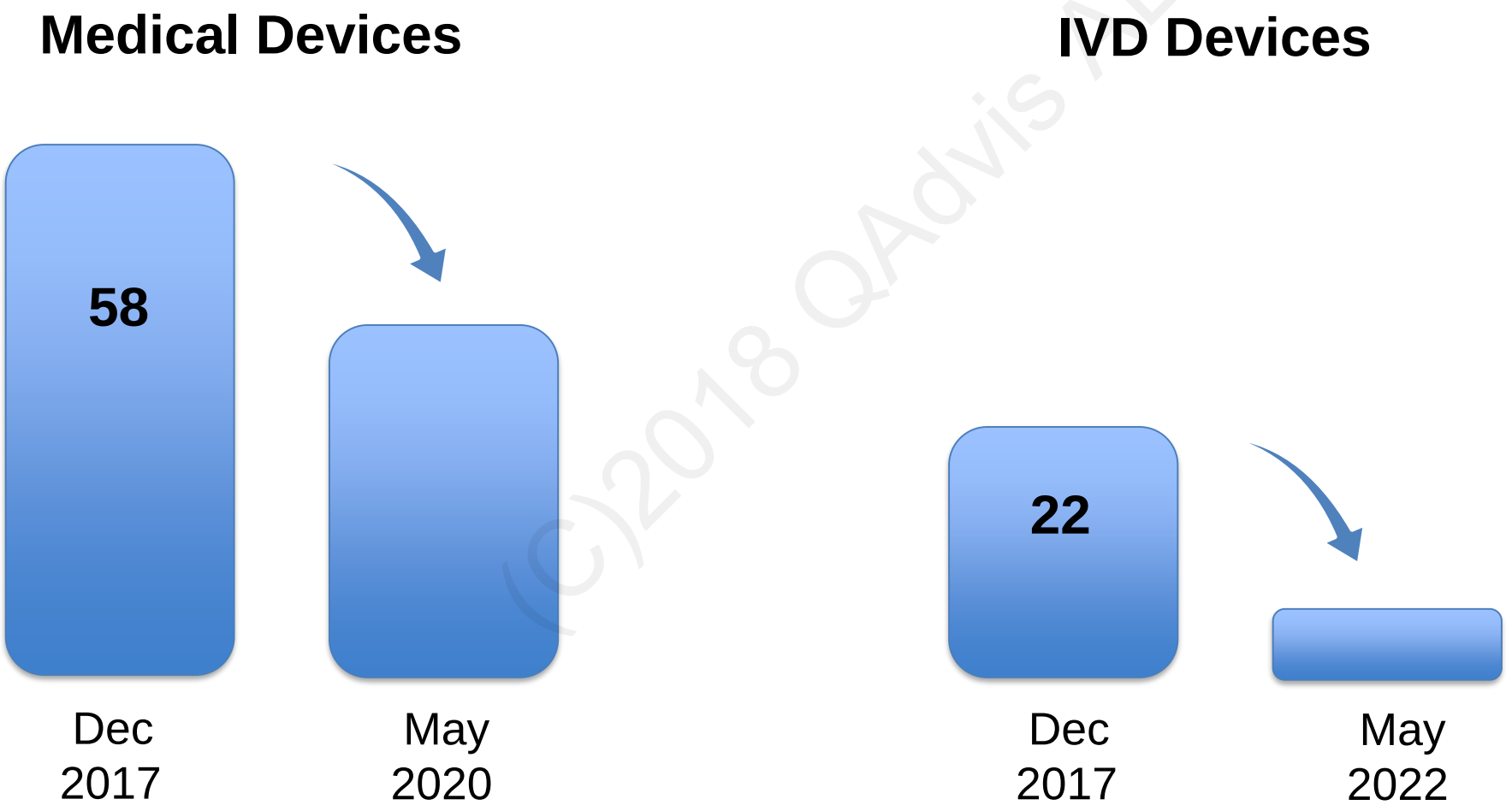
Major change in IVD industry



Busy times ahead



Notified Bodies – Dropouts and limited scope



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Questions?

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