**The regulatory storm is approaching the MedTech industry**

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MDR for Föreningen Svensk Dentalhandel – 2018-04-25
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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
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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**Presentation of the speaker 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 and IEC, 82304-1
SW Expert EU SW Workgroup
Chairman of board of QAdvis

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## Agenda

- Introduction and background
- Medical Device Regulation (MDR) highlights
- Conformity routes and classification
- Technical Documentation
- General Safety and Performance Requirements (GSPR)
- Quality Management System (QMS)
- Timelines and implementation
- Additional information
- Questions and answers
- QAdvis services

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**Background**

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## Major changes for medical device and IVD device industry are ahead of us

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

Affecting <u>all</u> stakeholders: manufactuers, distributors, competent authorities, notified bodies, and many more
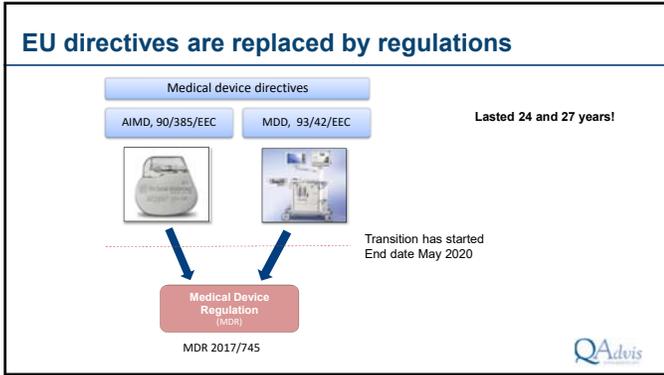
**At the same time!**

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## EU directives are replaced by 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

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## EU directives are replaced by regulations also for IVD products

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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## EU Regulations for medical devices are not far away, two years

Medical Device Directive 93/42/EEC and

Active Implantable Medical Device Directive 90/385/EEC

are replaced by

**Medical Device Regulation 2017/745**

End date May 2020

Lasted 24 and 27 years -> RIP

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## EU Regulations for IVDs have five years transition time

In-vitro Diagnostic Medical Device Directive 98/79/EC is replaced by

**In-vitro Medical Device Regulation 2017/746**

End date May 2022

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## EU - Medical Device Regulation 2017/745 (MDR)

All <u>current</u> CE-marked devices need to be re-CE marked to
  survive 2020 + (4 years for class Im, Is or higher if "unchanged")

All <u>new</u> devices must meet MDR after May 2020 to be CE marked

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

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## Notified Bodies need to reapply for MDR

All Notified Bodies lose accreditation for MDD, in May 2020
Need decide and apply for designation for MDR, in Nov 2017

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## You need to be aware – and act

Strategy for <u>current</u> product portfolio - regulatory aspects

Strategy for <u>future</u> product portfolio – regulatory aspects

**Time is limited!**

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## MDR is very dense with information

It takes time to read it, digest and understand

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## 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, Unique Device Identification (UDI)

⇒ Much stricter classification for Software as Medical Device (SaMD)

### MDR classification, several changes

**Examples**

**Rule 20 – new rule**
Inhalation of medicinal products
- Class IIa or IIb

**Rule 21 – new rule**
Substances intended to be introduced into the human body
via a body orifice or applied to the skin – Class IIa, IIb or III

**Conclusion:** Change of class? Need for NB? (Portfolio strategy)

NB = Notified Body

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### The expectations on Clinical Evaluations will be challenging to fulfil

- Update Clinical Evaluation reports
- Need sufficient clinical data
- Claim equivalence with other products much more difficult
  - require continuous access to technical documentation and a contract with the (competitor) manufacturers
  - technical documentation referenced shall be based on MDR

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

PMCF = Post Market Clinical Follow-up

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### Prepare your company for the MDD to MDR transition

Analyze and form your MDR (and IVDR) strategy for your products



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## Medical Device Regulation affect many roles

Some important distribution/import aspects

⇒ New requirements for <u>distributors</u> to verify compliance of products, report

⇒ New requirements for <u>importers</u> to verify compliance of products

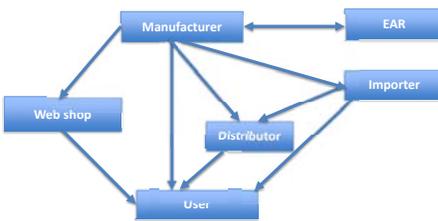⇒ New requirements for <u>authorized representatives</u> to verify compliance of products

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## A distribution chain can be complex
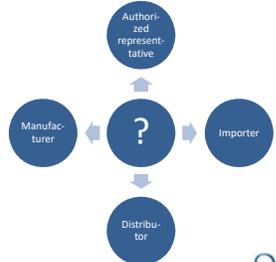


EAR = European Authorized Representative

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## Who is responsible for what?

**Your QMS must handle it all**

Quality contracts with
distributors,
suppliers,
authorized representatives,
importers, etc.

Eudamed!



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## Your Quality Management System (QMS) needs to be updated

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

ISO 9001:2015 end of transition period in Sept 2018

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## CE-mark is used also outside EU

CE-mark used in several other jurisdictions as means for regulatory approval

Declaration of Conformity (DoC)

EC certificate

**Need to confirm with each country**

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## Medical Device Single Audit Program (MDSAP)

Quality system audit harmonization initiative to satisfy the requirements of multiple regulatory jurisdictions.

Current participants: USA, Brazil, Canada, Japan, Australia

Canada requires MDSAP from 1st Jan 2019 (CMDCAS removed)

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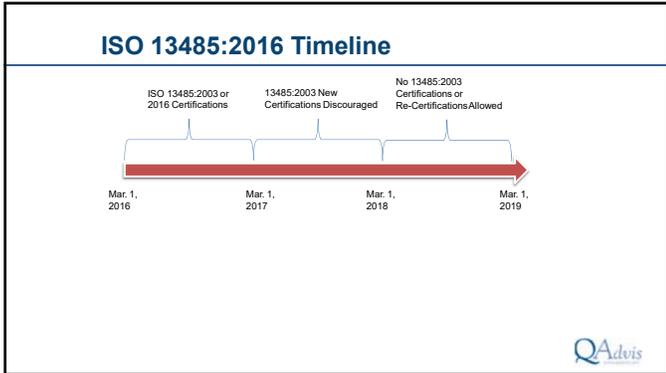## ISO 13485:2016 Timeline



## ISO 13485:2016 and MDSAP Timeline



## Combined Timeline

## Stormy times ahead

ISO 13485:2016

Mar. 1, 2016 | Mar. 1, 2017 | Mar. 1, 2018 | Mar. 1, 2019

MDSAP

Jan. 1, 2016 | Jan. 1, 2017 | Jan. 1, 2018 | Jan 1, 2019

EU MDR and IVDR

May 25, 2020

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## Stormy times ahead

ISO 13485:2016

Mar. 1, 2016 | Mar. 1, 2017 | Mar. 1, 2018 | Mar. 1, 2019

MDSAP

Jan. 1, 2016 | Jan. 1, 2017 | Jan. 1, 2018 | Jan 1, 2019

EU MDR and IVDR

May 25, 2020

ASEAN Medical Device Directive (AMDD)

General Data Protection Regulation (GDPR)

May 25, 2018

Brexit

March 29, 2019

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## Prepare your company for the MDD to MDR transition

Analyze and form your MDR strategy to meet the timelines

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## Brexit add more uncertainty and additional work

**UK based Notified Bodies**
(move before MDR=> new number)

**UK based Authorized Representatives**
(massive drop out or move to EU)

**Will UK adopt a UK-version of MDR
and IVDR or something else?**

**Will UK be part of Eudamed database?**

**Specific vigilance reporting to UK?**

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## Notified Bodies will drop out or limit their scope

**Medical Devices**

**IVD Devices**

Will your NB survive?

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Dec 2017    May 2020

Dec 2017    May 2022

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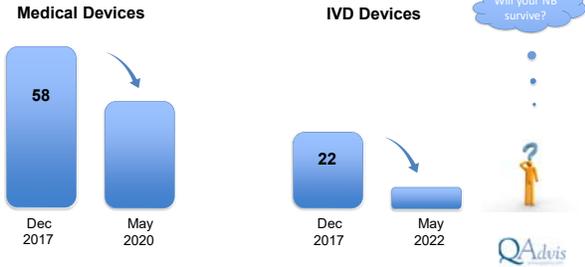
## Notified Bodies – Drop of number and scope

**Uncertainty**

- Which NB:s will apply for designation for MDR &IVDR?
- What scope will they apply for?
- Company product range may need 2 or more NB:s
- Shortage of trained qualified personnel
- Race for NB:s
- No NB certification in time = no CE mark

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## Medical Device Regulation – highlights

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### Delegated acts - Implementing acts

- **Delegated acts**

  Acts used to modify or amend the regulation.

- **Implementing acts**

  Acts used to clarify and explain how the regulations should be interpreted and used.

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### Common specifications (CS)

- When there are no harmonized standards or the harmonized standards are not sufficient, the Commission can adopt a common specification

- For example for devices with non-medical purpose and single use devices to be re-processed

(Article 2 (71))

### A person responsible for regulatory compliance is needed

- Manufacturer shall have available within their organization at least one person responsible for regulatory compliance.

(Article 15)

### Additional products covered by MDR

- Annex XVI defines products without an intended medical purpose.
- Common specifications is to be developed for these product groups.

(Article 1 (2) / Annex XVI)

### Eudamed

EUDAMED
(Article 33)

| Registration of devices | Electronic system on notified bodies and on certificates of conformity | Electronic system on vigilance and on post-market surveillance | Electronic system on market surveillance | Electronic system on clinical investigations |
|---|---|---|---|---|
| (Article 29) | (Article 57) | (Article 92) | (Article 100) | (Article 73) |

UDI Database (Article 28)

Electronic system for registration of economic operators (Article 30)

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## Unique Device Identification (UDI) system



*"Unique Device Identifier (UDI) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market."*

(Article 27)

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## UDI consists of two parts DI and PI

**UDI = DI+PI**



Machine readable format

Device Identifier (DI)          Production Identifier (PI)

Human readable format

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### Implant card is needed for more devices



Information allowing the identification of the device implanted

- Device name, serial number, lot number, UDI, device model, manufacturer and contact details to manufacturer, webpage
- Warnings and precautions to take
- Life time of device and necessary follow up

(Article 18)

### UDI is a multidisciplinary task
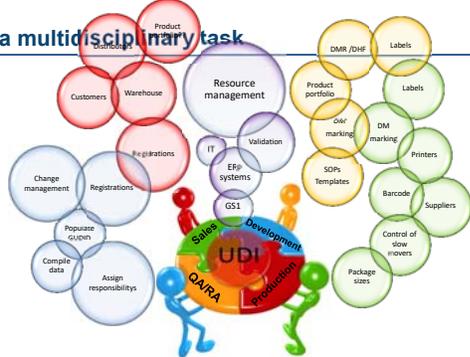


### Conformity routes

## Conformity routes – product classes are unchanged under MDR

Class III
Class IIb
Class IIa
Class I
(s, m, reusable surgical equipment)
Class I

- Conformity route to be selected for each device category – different routs to chose between depending on classification of device

- Involvement of Notified Body differs depending on assessment route and device classification

(Article 52)

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## Conformity routes are "renumbered" under MDR

- **Annex IX** – Conformity assessment based on a quality management system and on assessment of technical documentation

- **Annex X** – Conformity assessment based on type-examination

- **Annex XI** – Conformity based on product conformity verification
  - Part A – Production quality assurance
  - Part B – Product verification

- **Annex XIII** – Procedures for custom-made devices

(Article 52)

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## Classification

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## Classification rules overview

- Non-invasive devices: Rule 1-4
- Invasive devices: Rule 5-8
- Active devices: Rule 9-13
- Special rules: Rule 14-22

(Annex VIII)

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## Classification rules news and updates

- Rule 8 – addition
  Active implantable devices, breast implants or surgical meshes, joint replacement, spinal disc replacement implants – class III
- Rule 19 – new rule
  Incorporating nanomaterial – Class IIa, IIb or III
- Rule 20 – new rule
  Inhalation of medicinal products - Class IIa or IIb
- Rule 21 – new rule
  Substances intended to be introduced into the human body via a body orifice or applied to the skin – Class IIa, IIb or III

(For complete wording, see Annex VIII)

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## There is a new classification rule in MDR for SaMD – 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 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**

(For complete wording, see Annex VIII of MDR)

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## Rule 11 will change classification for many SaMD

- 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 Medical Device

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Technical Documentation

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### Technical Documentation - Overview

- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- DoC (Annex IV)
- GSPR (Annex I)
- Clinical Evaluation (Annex XIV)

(Annex I, II, III, IV, XIV)

PMS = Post Market Surveillance

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## Technical Documentation – Contents

| No. | Description |
|---|---|
| 1 | Device description and specification |
| 2 | Information to be supplied by the manufacturer |
| 3 | Design and manufacturing information |
| 4 | General safety and performance requirements |
| 5 | Benefit-risk analysis and risk management |
| 6 | Product verification and validation |

UDI, rationale for MD, classification

UDI, indication for MD, substances? importer?

Identification of all sites, suppliers and subcontractors

More: Update structure, DoC

Clinical evaluation, additional requirements on substances

Make sure Annex I (1, 3, 8) is fulfilled

Update entire checklist!

(Annex II)

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# General Safety and Performance Requirements (GSPR) and more

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## General Safety and Performance Requirements (GSPR)- Overview

- Change from MDD Essential Requirements (ER) to General Safety and Performance Requirements (GSPR)
- Checklist recommended
- Method of compliance
- Reference to evidence of compliance

(Annex I)

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## GSPR are more detailed and demanding than Essential Requirements

- Risk based approach – Stronger connection to Risk Management
- Annex XVI products included (no medical purpose)
- Clinical evaluation requirement deleted from Annex I (ER 6a). Included in Article 61, Annex XIV and Annex II.
- Requirements for active implantable devices added
- Substances specified with limitations
- Risk of particles released
- Risks with software and IT environment

(Annex I)

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## Clinical Evaluation

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## Clinical Evaluation – Extent based on

- Nature
- Classification
- Intended purpose
- Risks
- Manufacturer's claims

(Annex XIV)

## Clinical Evaluation – Equivalence

May be based on equivalent devices

- Technical equivalence, and
- Biological equivalence, and
- Clinical equivalence

Sufficient levels of **access to the data** in order to justify their claims of equivalence

(Annex XIV, Article 61)

## Clinical Evaluation – Product Assessment

- Based on equivalence?
- Clinical evidence sufficient?
- Need of new clinical trials?
- Need of PMCF?
- MEDDEV 2.7/1 Rev 4?
  - Guidance, not legally binding
  - State of the art?
  - Inspiration
  - Recommendation; Follow MEDDEV 2.7/1 Rev 4 and make sure that Clinical Evaluation according to MDR is fulfilled.

(Annex XIV, Article 61)

PMCF = Post Market Clinical Follow-up

## Quality Management System

### General obligations of manufacturers

Requirements on

- Quality Management System
- Manufacturing and design
- Clinical evaluations
- UDI system
- Risk management
- Technical documentation and DoC
- Vigilance
- Post market surveillance system

(Article 10)

DoC = Declaration of Conformity

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### Implementation

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### Implementation

GAP Assessment

| 1 7 MDR awareness | 2 Portfolio assessment | 3 - Assessment Route - TD - QMS | 4 - Notified Body - Economic operators - Global market | 5 Implementation plan | 6 Training | Audits |

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Additional information



Additional information for the manufacturer

- Information from the Commission
- Information from Competent Authorities
- Information from Notified Bodies
- Notified Body Operations Group (www.nbog.eu)



Conclusion

## MDR Conclusions

- MDR is published
- 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 evidence necessary
- Many products will be up-classified

(Annex VIII)

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## Make the plan, now!

- Gap analysis
- Get the fundings
- Action plan
- Execute the plan
- Review the plan quarterly

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## Thank you for your attention
## Questions & Answers

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## QAdvis services



- GAP analysis and implementation plan
- Quality Management System
- Auditing
- Technical Documentation
- Clinical Evaluation
- Risk management
- Courses
  - MDR
  - CE marking
  - ISO 13485:2016
  - Software validation
  - Risk management & SW risk management
- Internal trainings
- Product specific workshop

Contact
robert.ginsberg@qadvis.com

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## Training course, examples



**EU Medical Device Regulation Course**
MDD to MDR – Key changes and implementation
Prepare your organization for the transition

Our services include:
- Quality management support
- System development
- Clinical evaluation
- Medical device software specialist services
- Regulated software validation
- Quality and regulatory consulting
- Training
- European Authorized Representation

**Introduction and aim**
Your organization has an upcoming challenge in implementing the Medical Device Regulation (MDR). This will probably lead to many questions and concerns about how to make this work efficiently and value adding. Sign up for our interactive one-day course on the new Regulation, and learn about the changes and how to implement the requirements in your organization. Let QAdvis guide you in this work!