How to achieve MDR Compliance for Medical Apps

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MedtecLIVE

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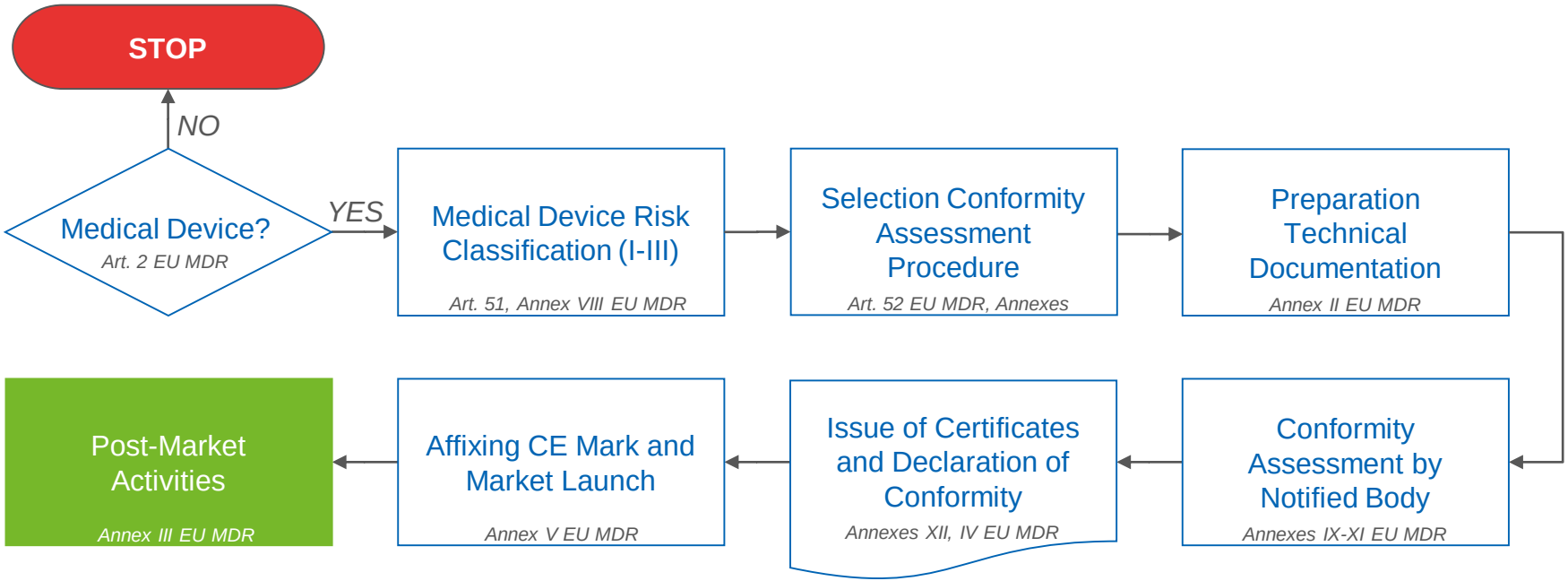
VDE

Let us look at a real-life example of a medical app looking for EU market access!

I want to place a medical app on the European market. What are the main steps?*

* Example taken from „Manual on borderline and classification in the community regulatory framework for medical devices" Version 1.20 (10-2018)

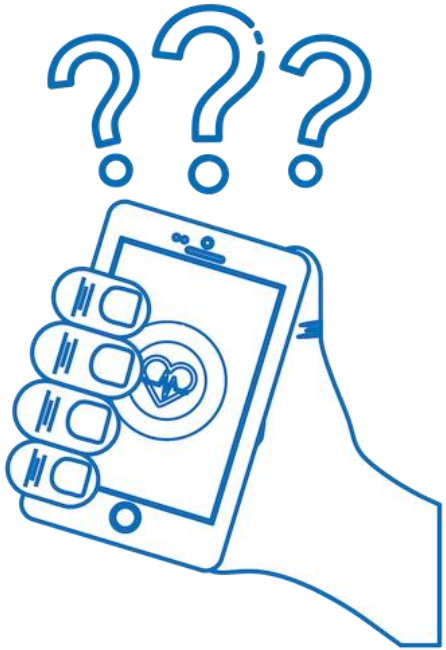
Road to Market Access for Medical Software



OK, that‘s an good overview.
Can you go in more details?

Tell us more about your app.
What is the intended purpose? Then we go to the first step…

Check whether your App is a Medical Device



1. Specify the intended purpose

Intended medical benefit	Functional principle	Intended use context	Intended user

2. Check if your software meets the medical device definition in Art. 2

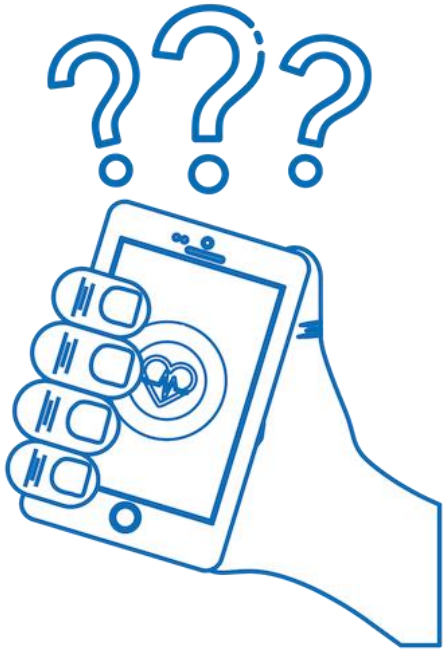
- Are the software output data used for a **medical purpose**?
- Have you used **keywords** as “alert, analyze, calculate, control, detect, diagnose, interpret, convert, measure, control, monitor, or amplify”?
- Does the software **change or interpret** its input data?
- Is the software intended to be used for or on **humans**?

The intended purpose encompasses the initial assessment (analysis) by the patient and not just data storage.

Your app is definitely a **medical device**!

More information on VDE Medical Software!

Check whether your App is a Medical Device



1. Specify the intended purpose

Mobile **software application** for the **initial visual analysis of moles** by the patient using a computer image processing technology.
It is not suitable for a definitive diagnosis of skin cancer.

2. Check if your software meets the medical device definition in Art. 2

- Are the software output data used for a **medical purpose**?
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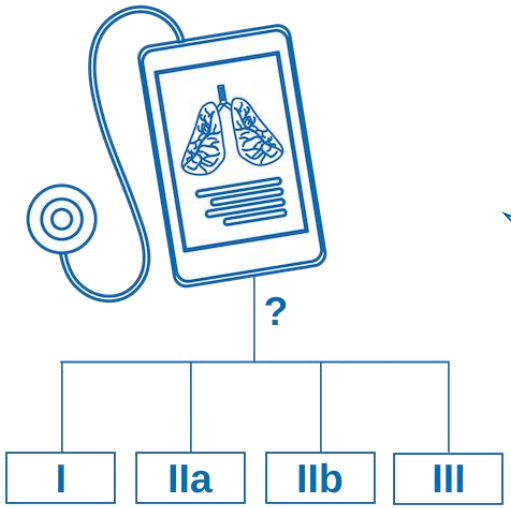
What Risk Class does my App belong to?



1. Check the criteria of rule 11 in Annex VIII 6.3 for stand-alone software

Does the software provide information to be used to take decisions with **diagnosis or therapeutic purposes**?

Yes, the “app assesses the probability that the scanned mole is a melanoma in order to support early diagnose of skin cancer”.

May decisions cause **death** or **irreversible deterioration of a person's state of health**? May decisions cause **serious deterioration of a person's state of health** or a **surgical intervention**?

No, although skin cancer is a serious disease, this particular app is used for an initial assessment by the patient only.

We suggest **class IIa!**

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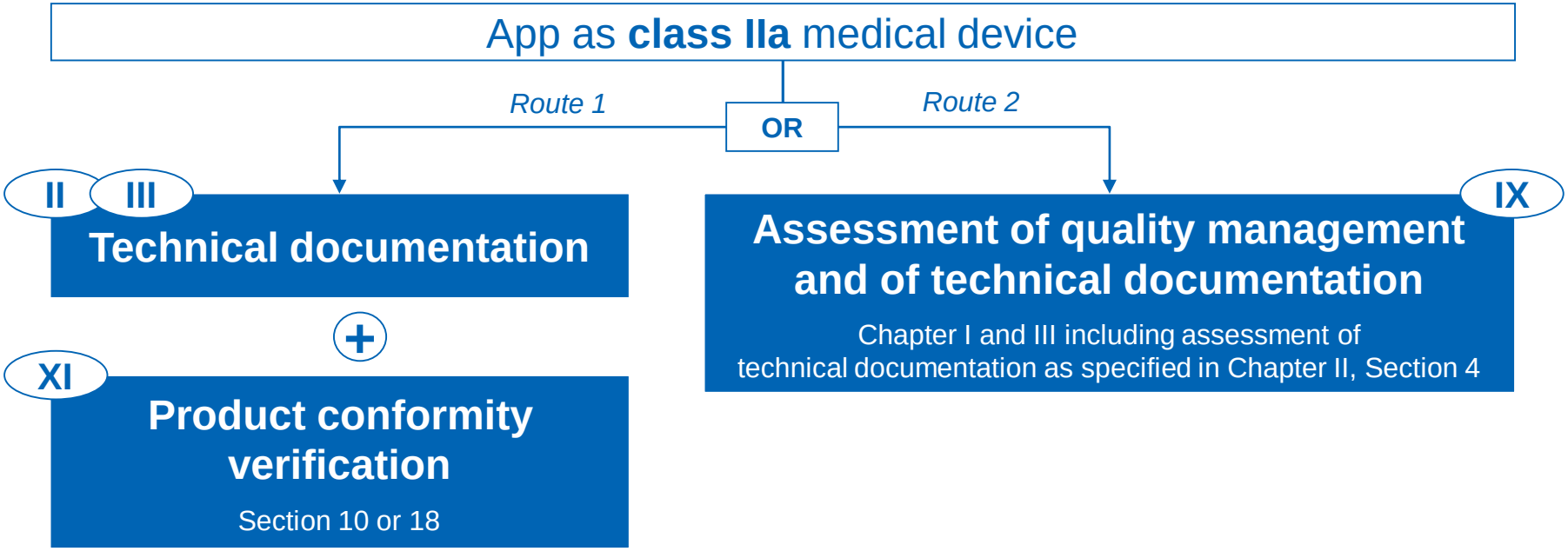
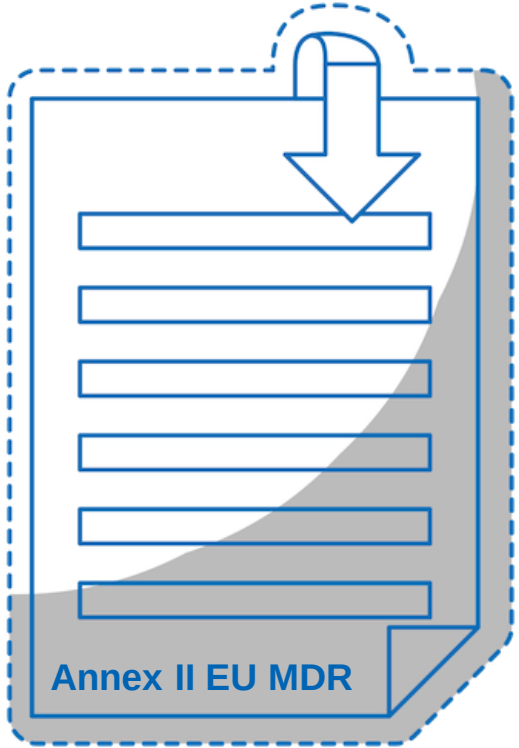
What‘s the right Conformity Assessment Procedure?



Requirements on Technical Documentation tell you what to do



1. Device description and specification	What kind of medical device do you have?
2. Information to be supplied by manufacturer	What information are you providing?
3. Design and manufacturing information	How is it designed and manufactured?
4. General safety and performance requirements	How did you meet the requirements?
5. Benefit-risk analysis and risk management	How did you manage the risks?
6. Product verification and validation	How did you demonstrate conformity by tests and studies?

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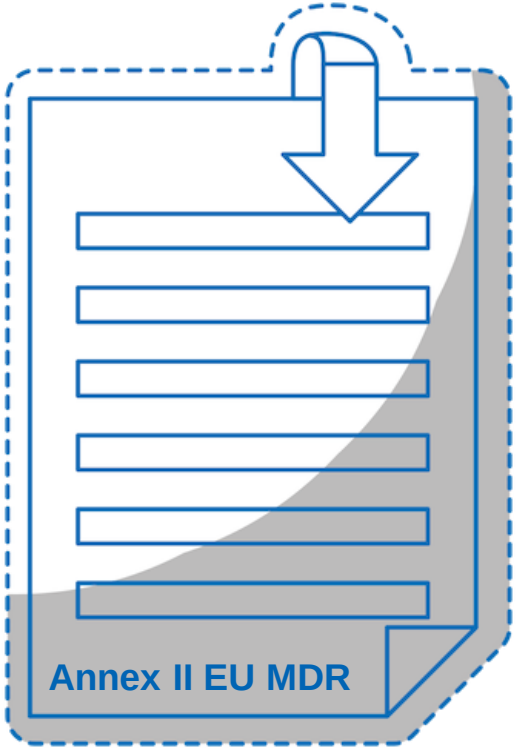
Anything Software-specific in Technical Documentation?



6. Product verification and validation

6.1. Pre-clinical and clinical data

- Test design
- Test or study protocols
- Methods of data analysis
- Data summaries
- Test conclusions

Software verification and validation

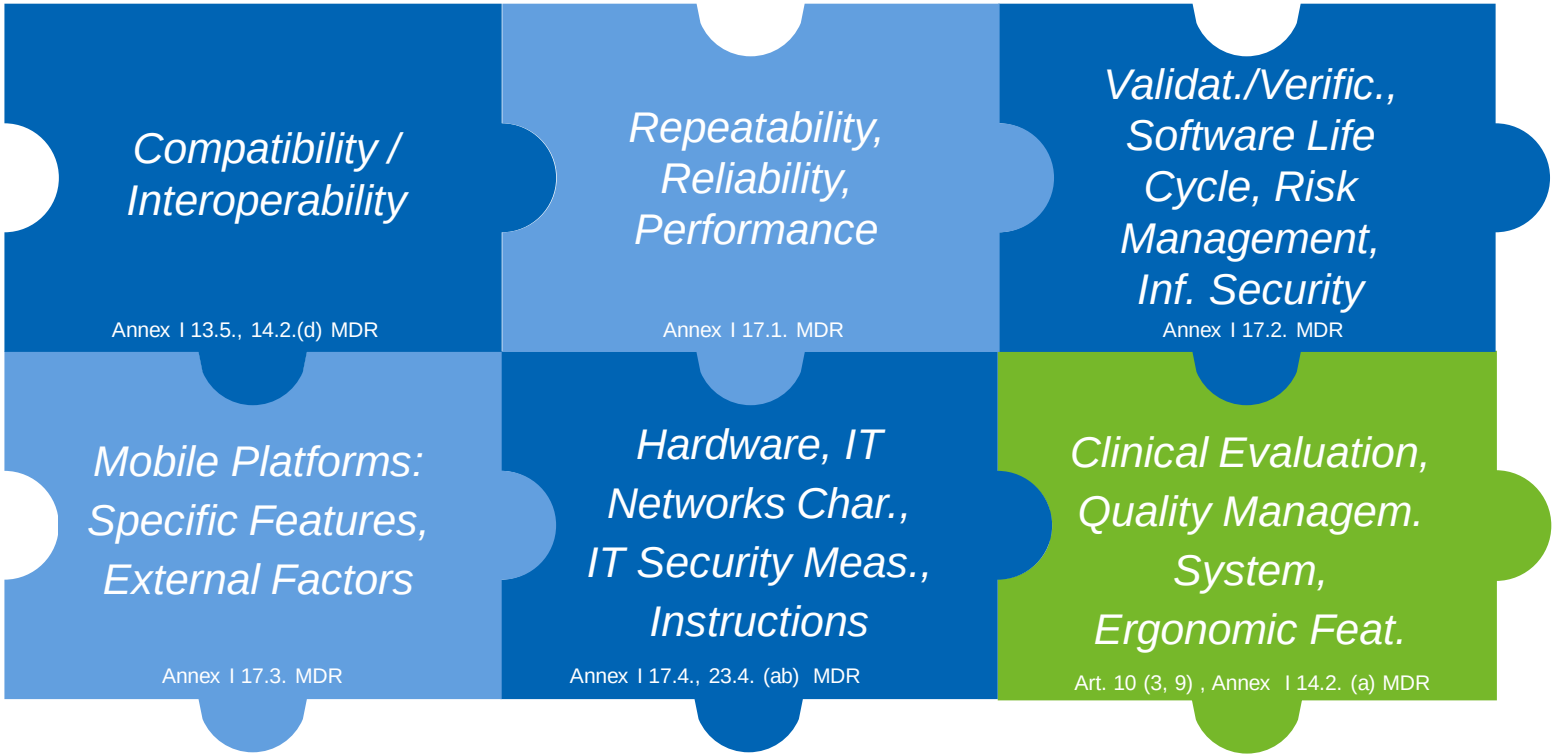
- Tests performed in both in-house and in a simulated or actual user environment
- shall also address all different hardware configurations and, where applicable, operating systems

How do I establish the link between the requirements for my software and standards?

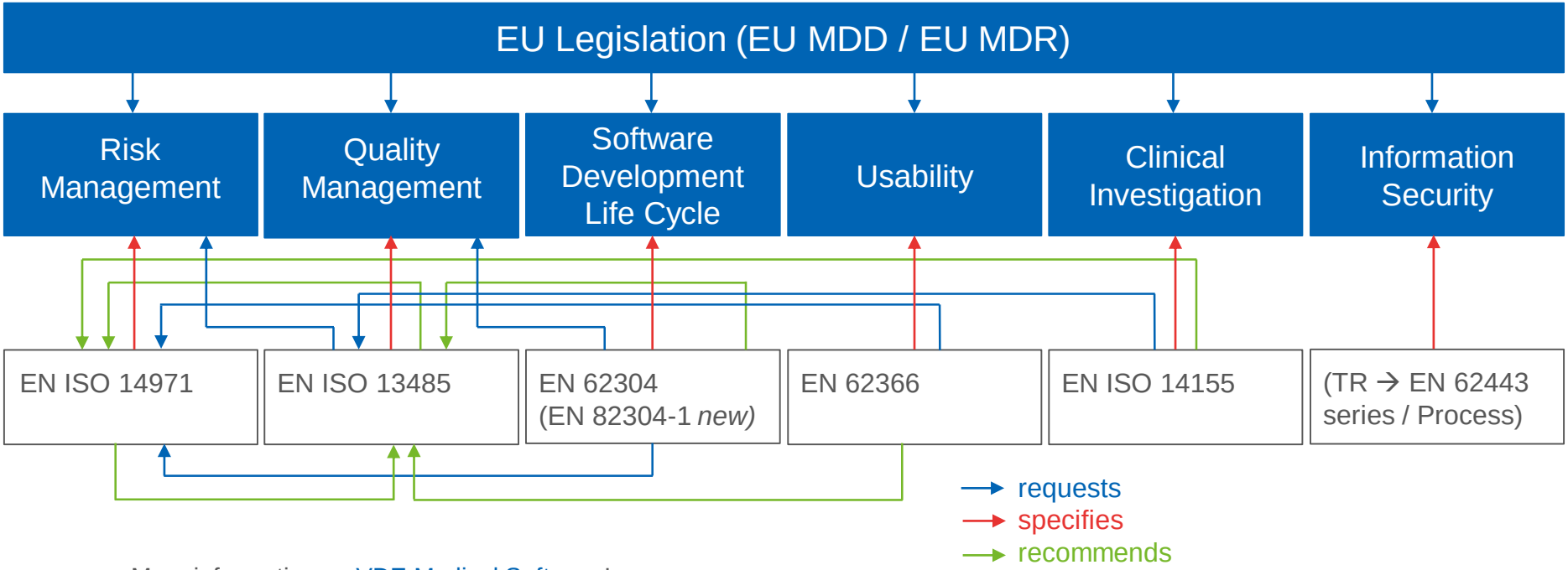
First, you identify general requirements for all manufacturers and products. Second, you identify requirements specific for your software!

Identify the relevant* Requirements

* examples



Apply the respective Standards



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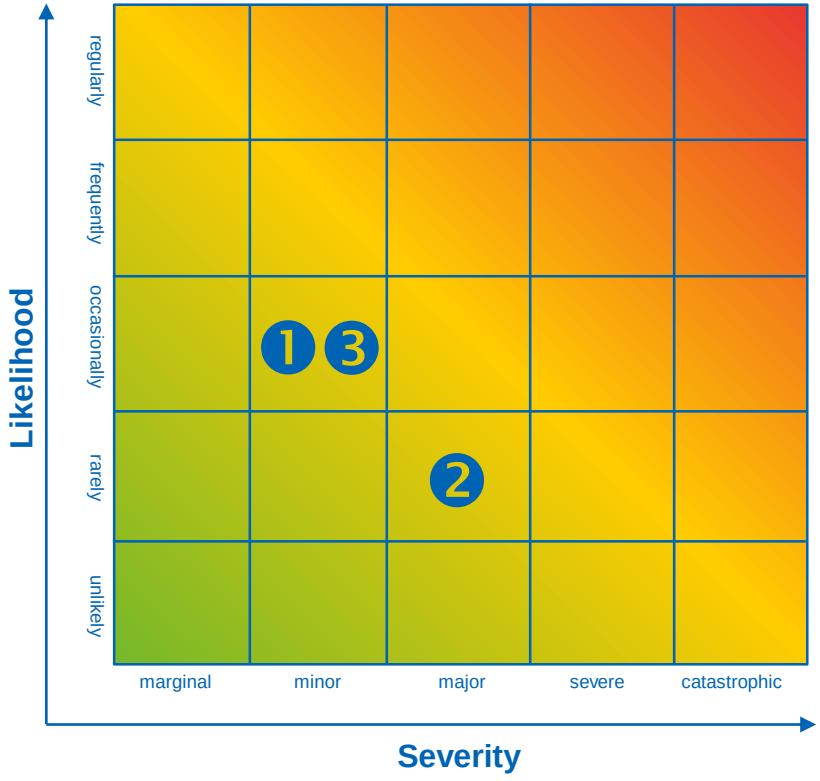
Risk management is a key requirement, isn’t it? Can you give me some examples of typical risks and how to control them?

Of course, we show you three examples in a risk matrix!

Possible identified Risks



1 False-positive results

Diagnostic algorithm failure

Software failure

2 False-negative results

Diagnostic algorithm failure

Software failure

3 Operator failure

Bad image quality

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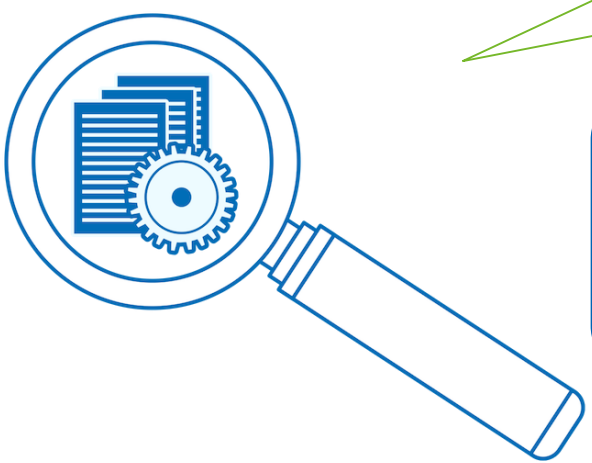
How you could deal with the identified Risks

	Risk Control				
	Verification	Clinical Trial	Human Factors Validation Testing	Labeling	Training
False positive results	X	X	X		
False negative results	X	X	X	X	
User failure				X	X

Coming back to the conformity assessment: what is the role of the notified body?

That depends on the conformity assessment procedure you have chosen…

The Notified Body's Role in Conformity Assessment



We have chosen to establish a quality management system according to ISO 13485.

The QMS and the technical documentation are assessed by the Notified Body. If everything is alright you receive an "EU quality management system certificate" and an "EU technical documentation assessment certificate".

Now, you may go ahead with issuing the EU declaration of conformity and affixing CE mark !

VDE Medical Software

What we do

Get relevant expertise by reading our Blog, using the Q/A and browsing through the medical software Glossary.

Get Knowledge

Connect with international medical software experts in our Community and benefit from the experience of others.

Connect with Experts

Receive customized training and guidance from our Partners to implement all regulatory requirements for your project.

Receive Guidance

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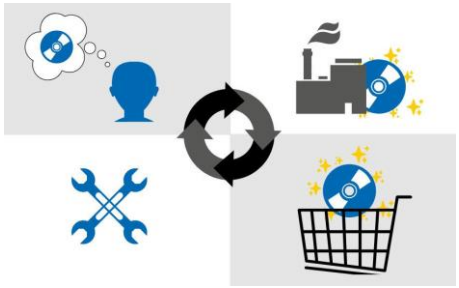
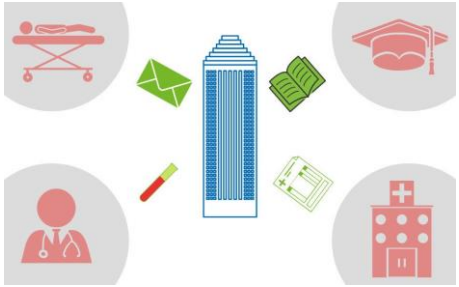
Upcoming Events



11. September 2019, Frankfurt am Main
Software Lebenszyklus: Wie erfülle ich die regulatorischen Anforderungen?
meso.vde.com/software-lebenszyklus/

17. September 2019, Frankfurt am Main
Sichere Cloud-Nutzung im Gesundheitswesen
meso.vde.com/sichere-cloud-nutzung-gesundheitswesen



23. September 2019, Frankfurt am Main
Medizinprodukte klinisch bewerten: Von MEDDEV zu MDR
meso.vde.com/klinisch-bewerten

Thank you
for your attention!

We are building the e-dialistic future.
Please join us.

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