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Navigating the uncertainty

Things to consider for different actors:
- Manufacturers
- Authorized Representative
- Importer/distributor

Have you assessed your situation?

This presentation gives some examples based on my experience with about 70 companies working with MDR across the world

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Sort out threats and weaknesses

- Risk management methodology gives you a structured way.
- What are the existing and foreseeable risks
- Trigger points
- Mitigations
- Alternative ways

Most companies typical do this but perhaps not in a documented way

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Manufacturers

Class I products – you own your destiny!

- MDCG 2019-15

Common issues:

- Product documentation does not meet MDR (or MDD)
- Quality system not meeting requirements/not existing

Biggest treat

- Authority actions with non conformities vs MDR
- Tender requirements about QA documentation

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Manufacturers

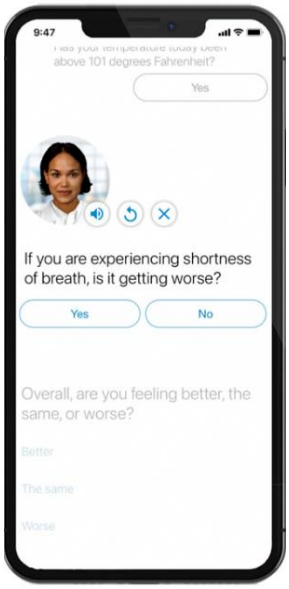
Class I products reclassified to IIa or higher

Common issues:

- Level of details in Quality system not enough (if existing)
- Level of details in product documentation not enough
- Audit readiness of the organization (competence)

Biggest treat:

- To Find a and handle the Notified Body
- Time to market, initial and for each “bigger” change
- Increased costs effecting margin
  - Initial and running costs



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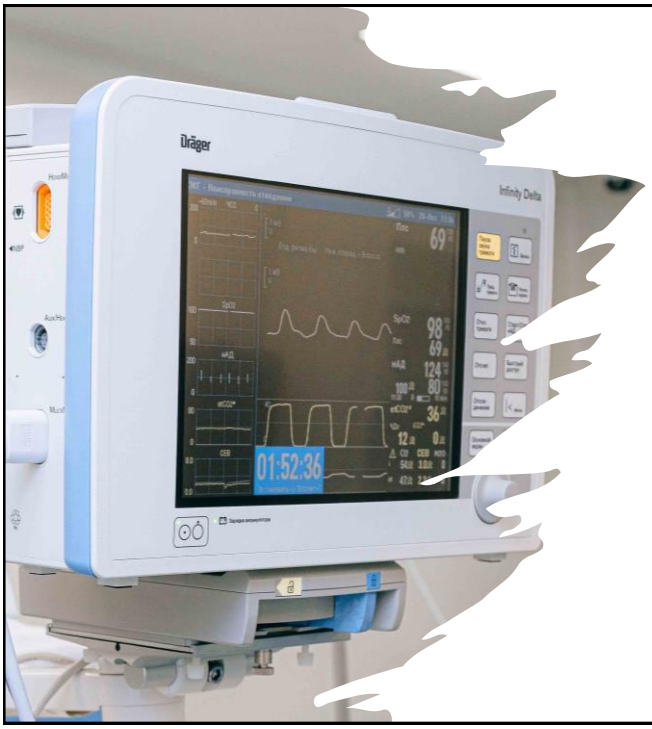

Manufacturers

Product(s) already have a Notified Body for MDD

Common issues:

- Notified Body have raised the bar
- Detailed level change

Biggest treat:

- Notified Body level of details
- Increased cost
- Time to market might be increased

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Authorized Representative

This is a big change

Must understand MDR in depth

- Technical documentation access
- Oversight QA system in practice
- Insurances
- PRRC requirements
- MDCG guidance expected soon

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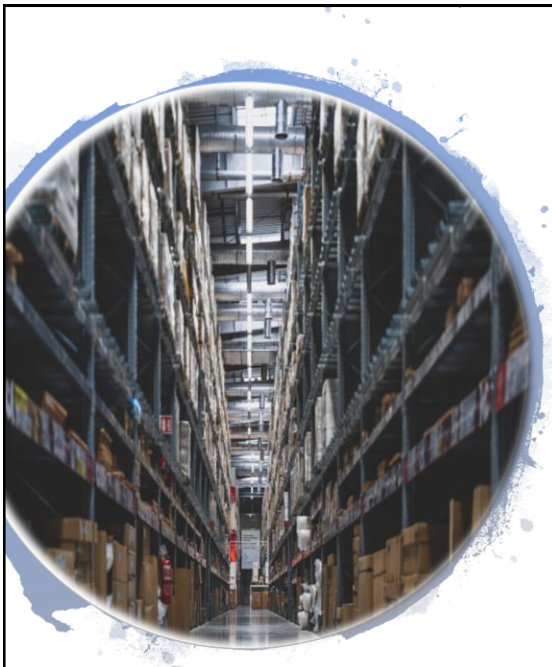

Distributor/importer

Formal requirements

- Should already been in distributor contracts, in MDD it was the manufacturers responsibility
- Traceability, PMS
- CE marking checks and transportation etc

- Only way to show this is through documentation – QA system

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Distributor/importer
- issues and treats

- Cannot demonstrate that activities have been done – person dependent
- Resource needs

- MDCG guidance 2021-27
- Relabelled or repackaged device MDCG 2021-26

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Complexity increased

- Regulation much more detailed than MDD
- Cover more actors (in Sweden)
- More Guidance documents than for MDD
  >25 guidance documents planned
  > 80 guidance documents exist

And then you have many other legislations….
WEEE, Rohs, REACH, GDPR, Export control,

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Key take away

- Gap and risk assessment key to secure business
- Each type of actors have typical ”issues” to look into
- Route to compliance will look different between companies

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