Spår:
Management

**Peter Löwendahl**
Styrelseledamot Swedish Medtech
Ordförande Regulatory Affairs, Swedish Medtech
#swedishmedtech

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**Lilian Nilsson**

Chef för Regelverk och vägledning inom enheten för medicinteknik på Läkemedelsverket

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2020-02-20

# Regulatory Summit - Management

Lilian Nilsson

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

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# Agenda

- Swedish Medical Product Agency's role (medical devices)
- Timelines MDR/IVDR and transitional provisions
- Market surveillance and vigilance
- Class I manufacturers



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# MPA's role – medical devices

- **Competent Authority (CA)** for MDR/IVDR
- **Market Surveillance**
- **Reports** of serious incidents and field safety corrective actions
- **Designated Authority (DA)** for MDR/IVDR



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# More responsibilities

- National legislation
- EU cooperation (CAMD, MDCG)
- Investigation of clinical trials
- Registration of actors/products
- Free Sales Certificate
- Questions from manufacturers, public, media etc
- External information (web, conferences, newsletter etc)



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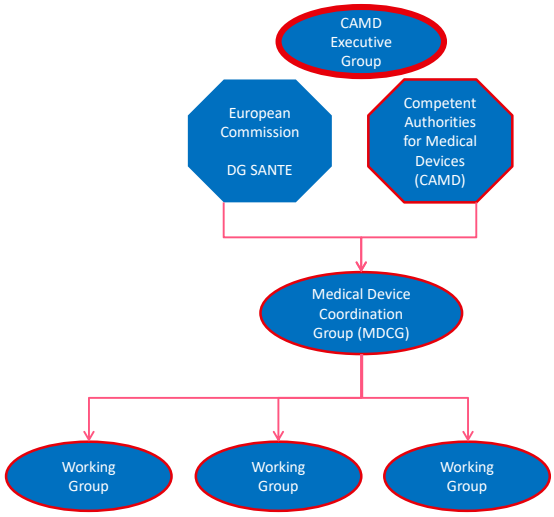
# European Commission and Competent Authorities




**MPA is represented in**

- CAMD
- CAMD executive group (lead)
- MDCG
- All 13 MDCG WG
- Several MDCG Task forces



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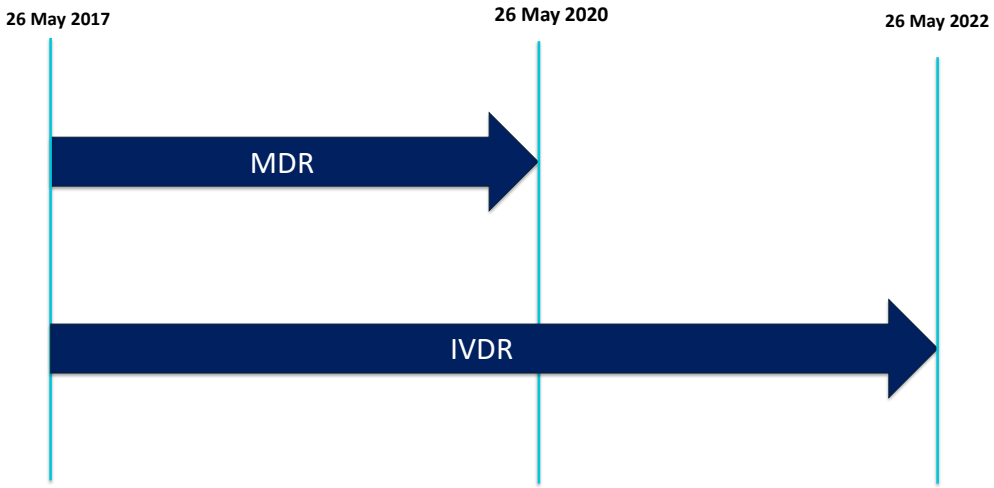
# Timeplan



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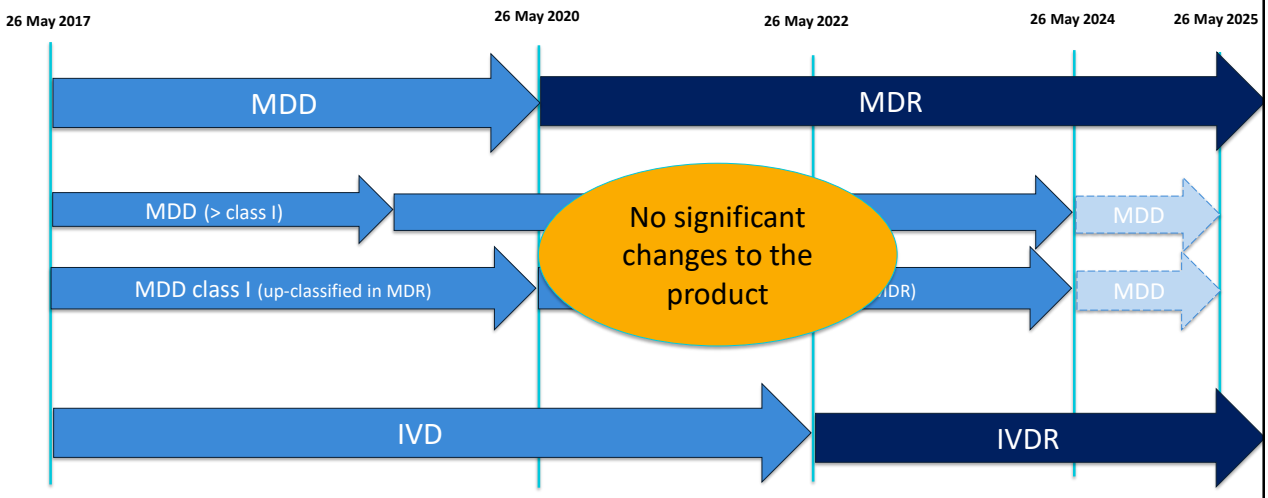
# Transitional provisions



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# MDD products from May 26, 2020 - some MDR requirements applies

*Article 120.3: However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply….*

**Post-market surveillance**

Art 83: Post-market surveillance system of the manufacturer
Art 84: Post-market surveillance plan
Art 85: Post-market surveillance report
Art 86: Periodic safety update report

**Market surveillance**

Art 93: Market surveillance activities
Art 94: Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
Art 95: Procedure for dealing with devices presenting an unacceptable risk to health and safety
Art 96-99

**Vigilance**

Art 87: Reporting of serious incidents and field safety corrective actions
Art 88: Trend reporting
Art 89: Analysis of serious incidents and field safety corrective actions
Art 90: Analysis of vigilance data

**Registration of economic operators**

Art 29: Registration of devices
Art 31: Registration of manufacturers, authorised representatives and importers



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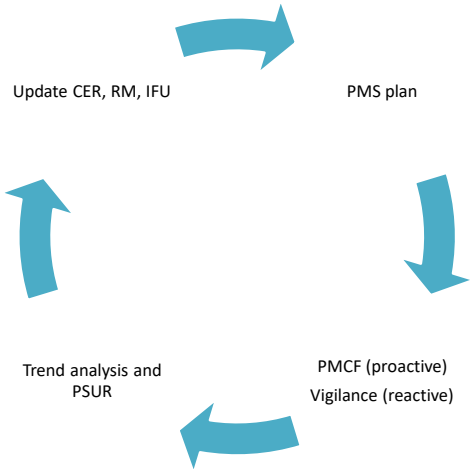
# Post-market surveillance




**Focus on proactivity in MDR**



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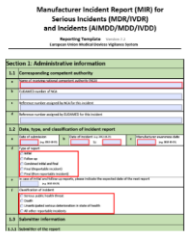
# Reporting of serious incidents and field safety corrective actions

Manufacturers shall report

- **any serious incident**
- **any field safety corrective**
- **trend reports**




Until EUDAMED is up and running the completed MIR:s shall be submitted to the CA


!



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# Class I manufacturers

- Integrate MDR in the Quality Management System (QMS).
- Meet the general safety and performance requirements
- Conduct clinical evaluation
- Prepare technical documentation
- Notified body needed?
- Prepare instruction for use and labelling
- PRRC - Person Responsible for Regulatory Compliance

**Guidance:** *https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en*



# PRRC - Person Responsible for Regulatory Compliance

The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the **quality management system** under which the devices are manufactured, before a device is released;

(b) the **technical documentation** and the EU declaration of conformity are drawn up and kept up-to-date;

(c) the **post-market surveillance** obligations are complied with in accordance with Article 10(10);

(d) the **reporting obligations** referred to in Articles 87 to 91 are fulfilled;

(e) in the case of **investigational devices**, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.

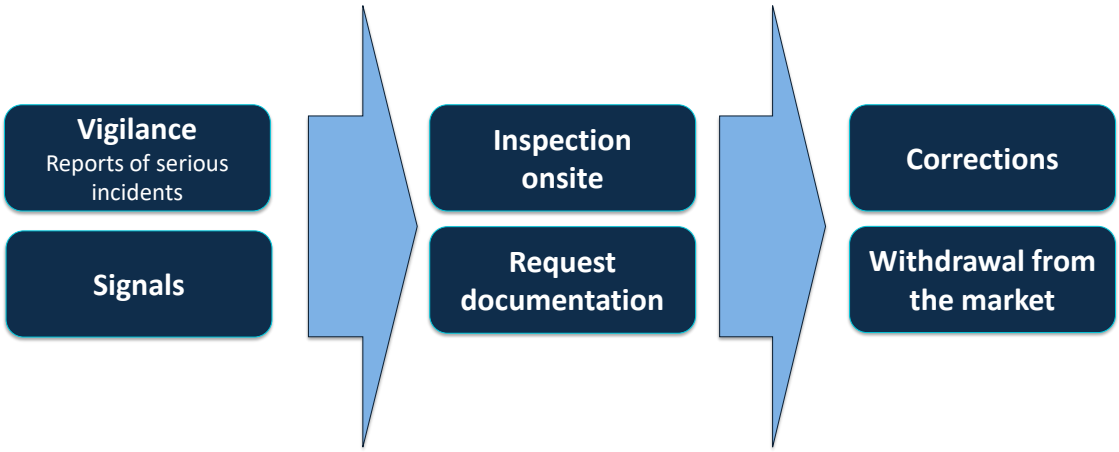
Qualifications defined in MDR (Article 15)

**Micro and small enterprises** …. shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal

**The responsibilities can be assigned to more than one person**

**Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance….**

# Market surveillance – risk based approach



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# Derek Nagelkerke

Senior Business Development Manager
BSI

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# EU Medical Device Regulation, Notified Body overview and update from BSI

Derek Nagelkerke
BSI Group the Netherlands B.V.

By Royal Charter



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# The Role of the Notified Body

- Conduct MDR conformity assessments
- Review Technical documentation
- On-site audits QMS

## What is the role of the Notified Body?

**The role of a Notified Body is to conduct a conformity assessment under the relevant EU Directives or Regulations. The conformity assessment usually involves an audit of the manufacturer's quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. The technical documentation is assessed against the Essential Requirements set out within the EU Directives or the General Safety and Performance Requirements (GSPRs) within the EU Regulations, and considers the relevant guidance set out by the EU.**

Once the Notified Body has determined a manufacturer has conformed to the relevant assessment criteria, it issues a CE certificate to show that the products assessed meet the requirements.

The manufacturer signs a Declaration of Conformity and applies the CE mark (with or without the Notified Body number).

IMPORTANT!
"The Notified Body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices. They must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications".

**Manufacturers** are free to choose a suitable Notified Body – ensuring that they are qualified and experienced with the product to be certified.

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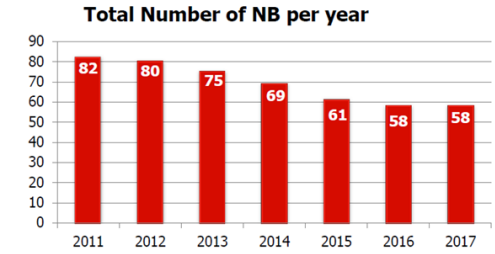
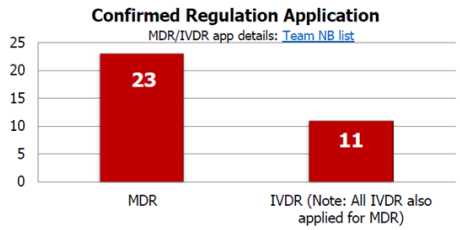
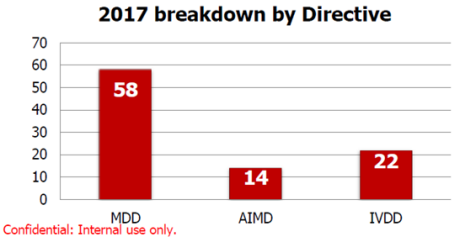
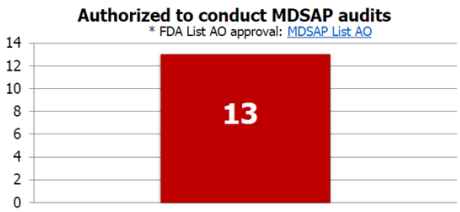
# Market Dynamics - #of Notified Bodies

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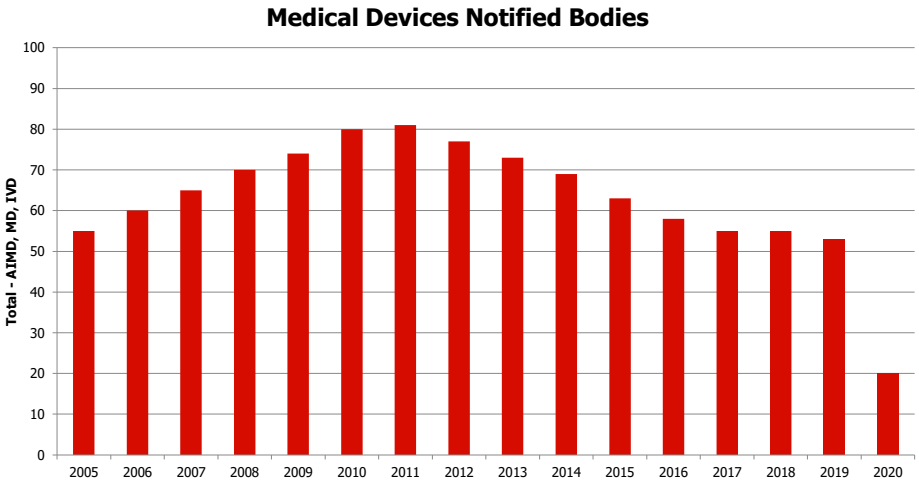
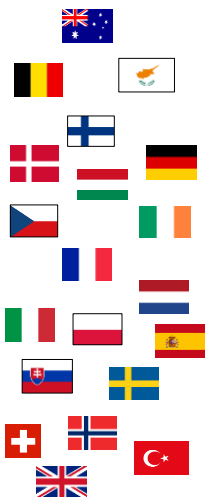
# NBMed – NBCG



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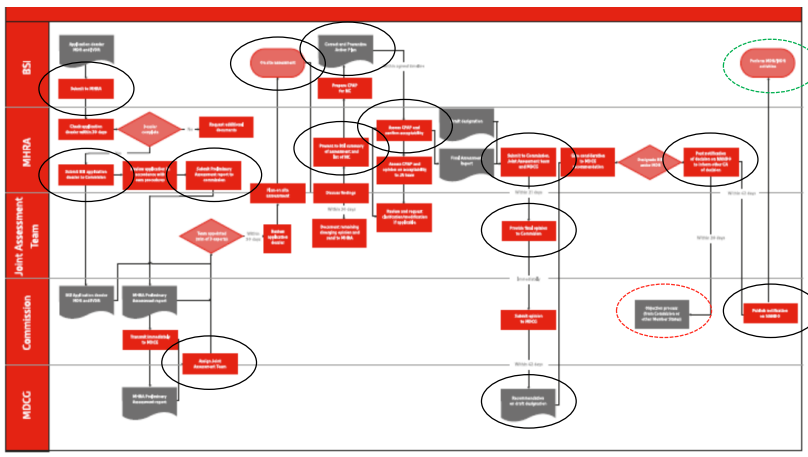
# EU MDR – Designation – Article 38-40

MDR:
- 27 Nov 2017
- 14 Dec
- 03 Jan 2018
- 10 Jan
- 09 Apr
- 16 Apr
- 10 May
- 24 Sept
- 17 Oct




07 Nov
30 Nov
19 Dec
Designation

△ **No Objections**

21 Jan 2019
Notification

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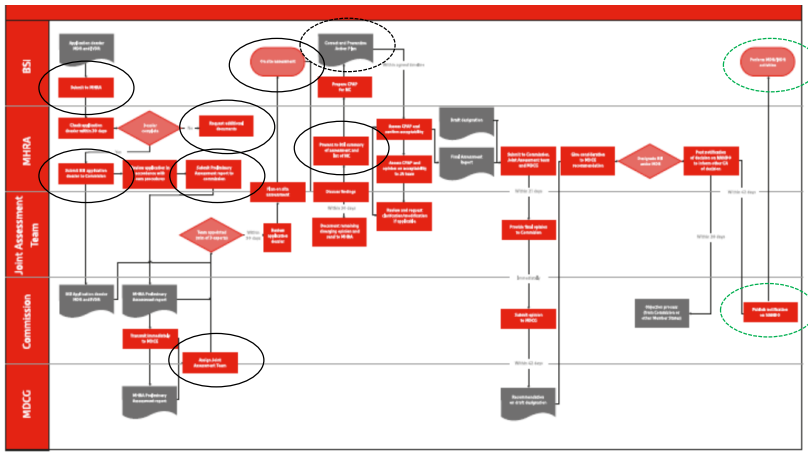
# EU MDR – Designation – Article 38-40

MDR:
- 27 Nov 2017
- 28 Dec
- 25 Sept 2018
- 26 Sept
- 28 Jan 2019
- 01 Feb

- 22 Feb CAP
- NC Close Out




Notification on 6th Nov 2019

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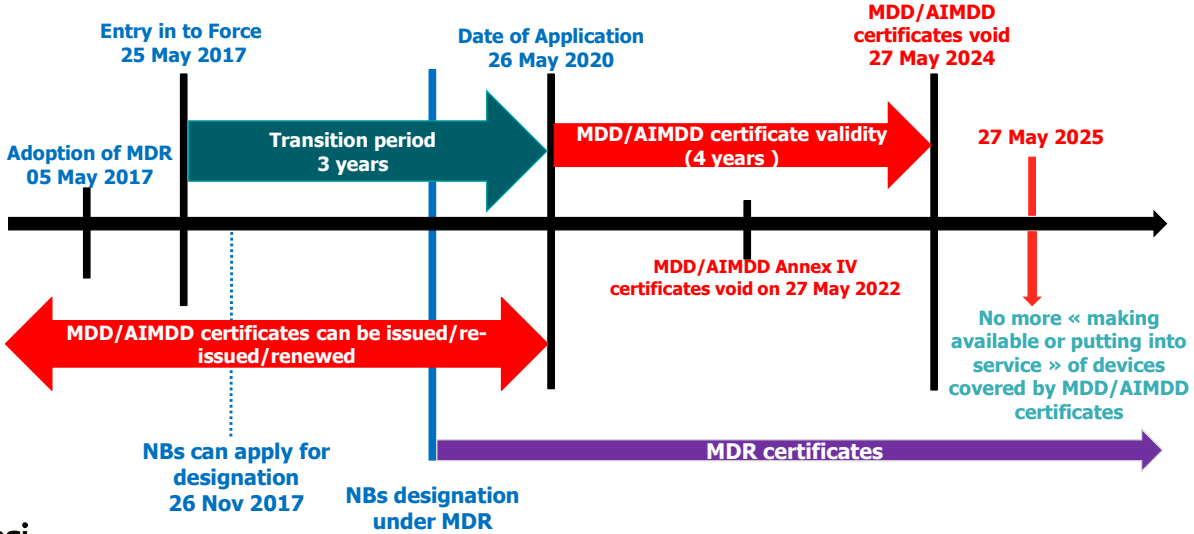
# MDR Transition (Article 120)




bsi.



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# Challenges facing NBs – BSI perspective

NUMBER OF AUDITS – DESIGNATION AUDITS, SURVEILLANCE AUDITS ETC

RAPID GROWTH – BSI MED DEV EXPECTED TO REACH ~750 BY END OF 2019

INFRASTRUCTURE OVERHAUL

PROCEDURAL CHANGES

TRAINING

COMPETENCIES

CHANGING INTERPRETATIONS AND NEW REQUIREMENTS BEING ADDED

MAINTAINING TWO NBS

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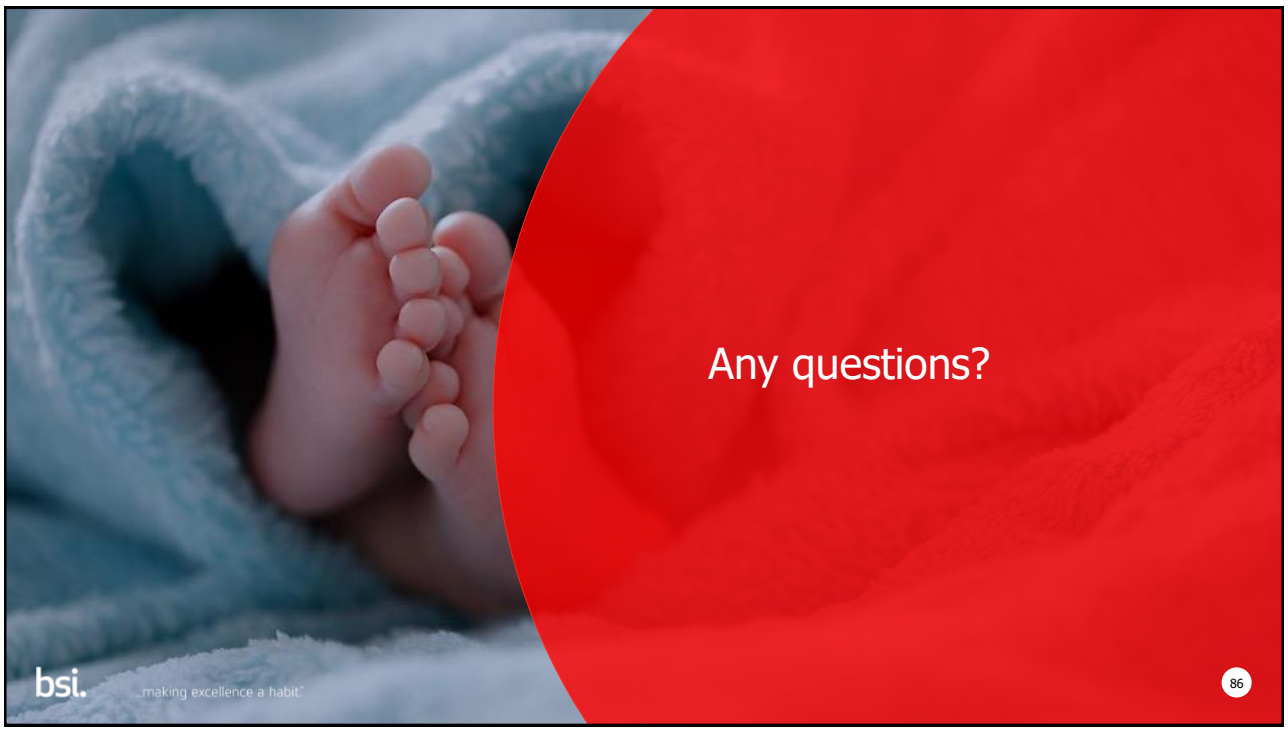


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# MDR and management considerations

Peter Löwendahl
February 2020

Hoff & Lowendahl

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## Agenda

- Navigating the uncertainty
- Key questions to ask now
- What do we know today
- What you already should be doing

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# Navigating the uncertainty

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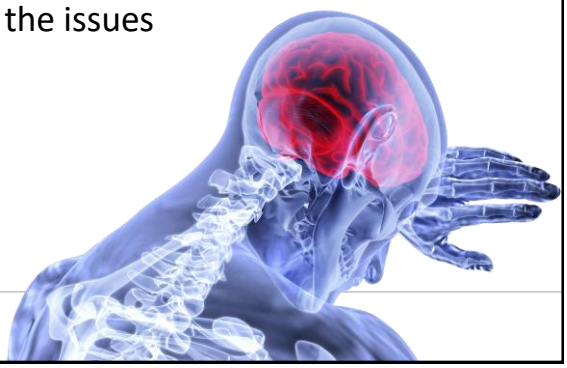
# Navigating the uncertainty

**Golden rule**

- Work with what you can, prepare for the worst

- Draw up a few scenarios to understand the issues
  - Worst case
  - Best case
  - The most realistic way



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## Navigate the uncertainty

- **Where are you in the process?**
- **Do you have a notified body for MDR?**
- **Are your products covered by MDD certificates?**
- **Do you need to make significant changes soon?**
- **Do you have correct level of documentation?**
- **Do you have a Quality system?**
- **……**

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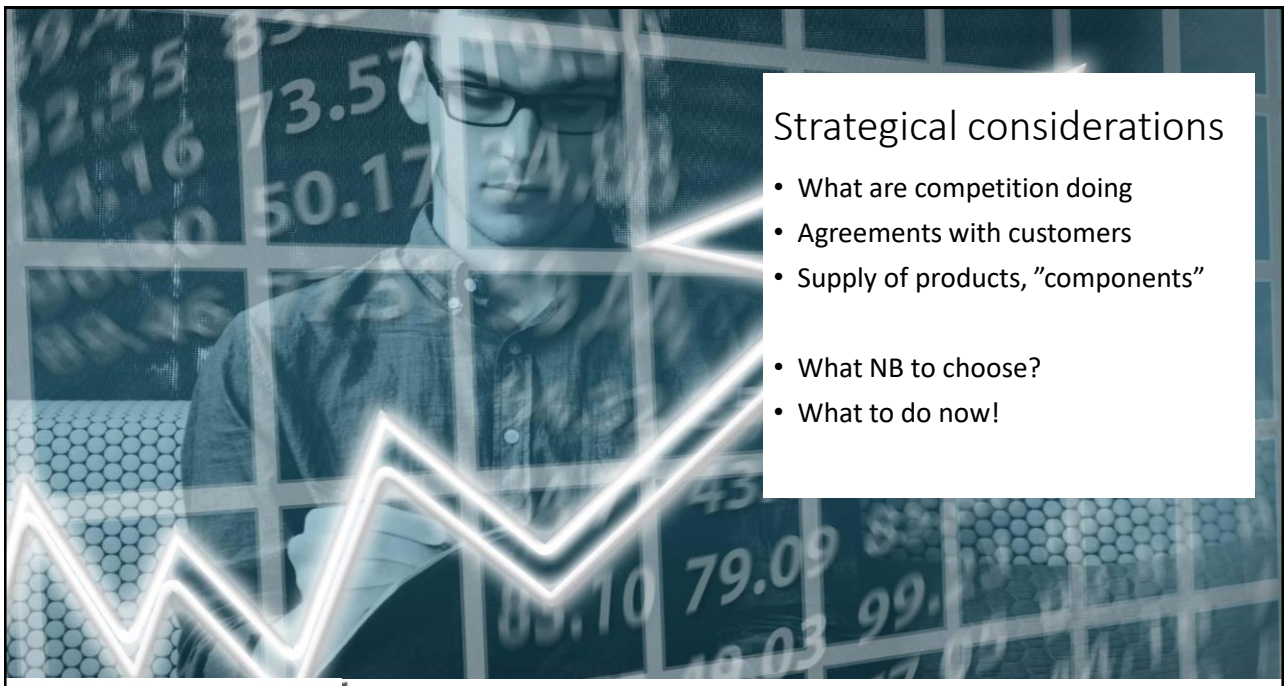

## Strategical considerations

- What are competition doing
- Agreements with customers
- Supply of products, ”components”

- What NB to choose?
- What to do now!

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# 3 key items from management perspective

**TRUST IS GOOD,**
CONTROL **IS BETTER!**

**WHERE ARE YOU IN THE PROCESS?**

WHAT CAN YOU DO NOW?

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# Tomorrow will come with surprises and changed plans!

Have you done what is needed?

EU commission and Competent authorities struggling to:

- keep products on the market, but
- keep the foundation of the new regulation intact


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# What do we know today

**- Is it clear on a higher level?**

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## What do we know today?

- Not everyone will have a Notified Body (NB)
- Reclassified products got prolonged transition time (Corregendum 2)
- You can use extension possibilities (MDD with NB)

- Eudamed not formally live, but have you secured Basic UDI - GS1
- Registration will most likely be on national level to start with

- Swedish law will not be implemented in time i.e MDR applies fully

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## Importers and distributors

**All applicable parts in MDR applies except**:

- Importers cannot check Eudamed
- National registration will not be required in Sweden (not from start at least)
- Many process and logistic challenges

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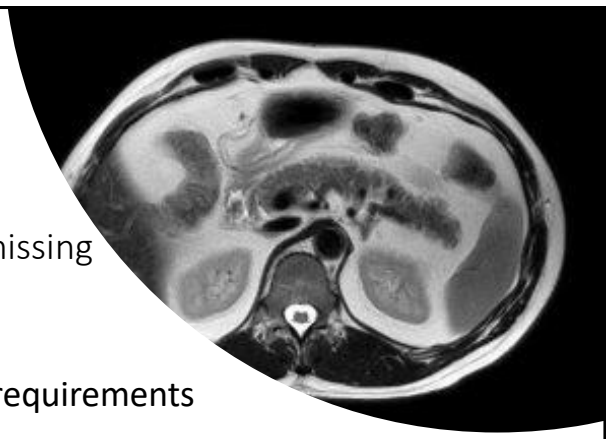

## Product and quality system requirements are known

- even though important guidelines are missing

There are no excuses not meeting these requirements

Meanwhile waiting for missing guidelines use MEDDEVs

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## Examples for class I manufacturers

**This you should meet already**

- **Product documentation**
- **Quality system**
- **Post market surveillance**
- **Clinical data**
- **Distributor/importer controls**

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## Examples for products with Notified Body

**This you should meet already**

- **Post market surveillance**
- **Distributor/ importer controls**
- **Significant changes**

**<u>Exceptions for MDD transition</u>**

- **Product documentation**
- **Quality system (class 1s and m)**
- **Clinical data**

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- What you already should be doing
  - Climbing the mountain?

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## Prepare for Notified Body

Make sure you have evidence that you have tried to get a Notified Body (and not only one)

Your documentation must meet new requirements when you find one!

A second opinion of where you are!

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## Meeting the deadline!

- What can you do

- You will not find a bunch of consultants out there
  - or loads of people to hire
    - But help with guidance
    - Training
    - Gap analyse
    - Prioritizing
    - Crash management
    - Long term solution
    - Have you signed up/appointed a Regulatory Designated person!!

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## Key take away

- Ensure you are active getting latest news and interpretations
- Have an ongoing project to keep control
- Do what you can and document this

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www.lowendahl.eu
peter@lowendahl.eu
Phone Int + 46 (0) 722-313355



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