Innovation challenges for orthopedic device manufacturers under the new EU MDR – A notified body perspective

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Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.

Who am I?

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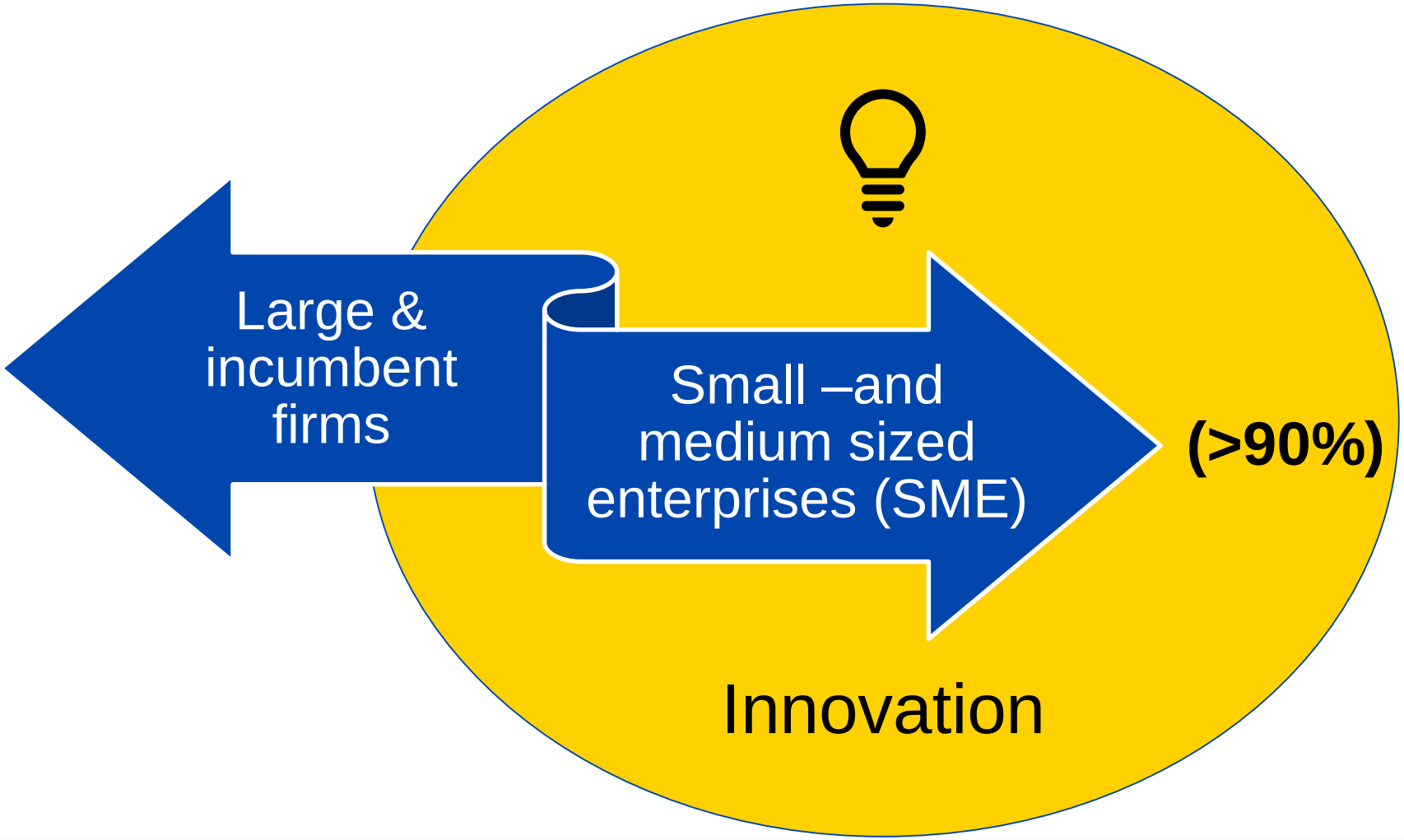
Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.

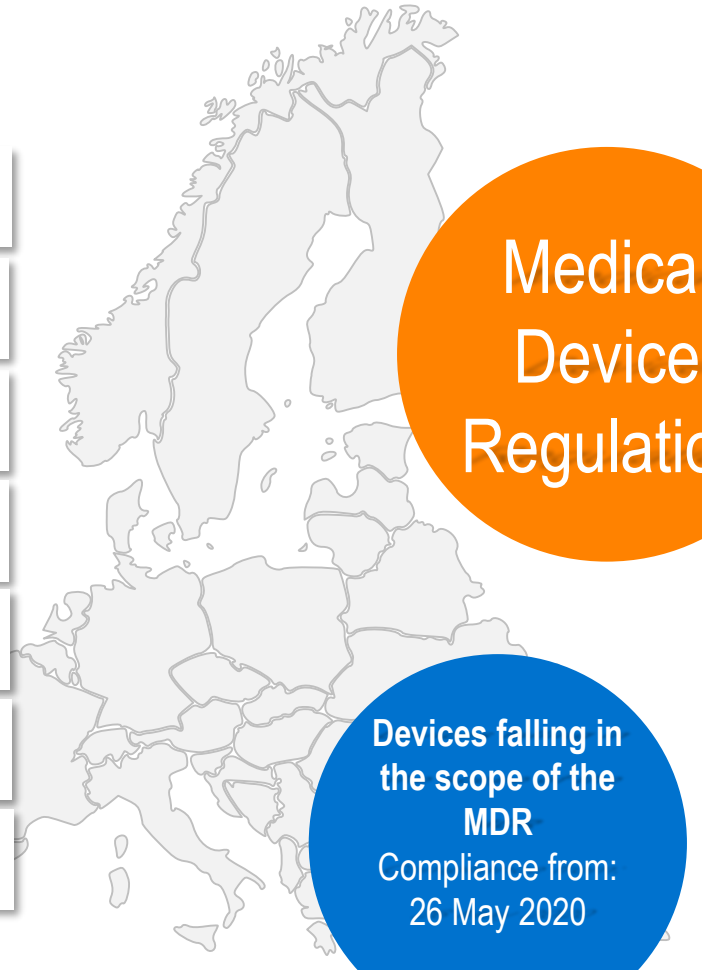
This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.

Innovation in the Medical Device Industry



What is happening when in EU Medical Device Regulation?

2008	Commission: consultation on medical device framework
2012	Commission: proposal for new MDR
2014 Q2	Parliament: position on MDR
2015 Q3	Council position on proposed Regulation
2015 Q4	Trilogue: Commission, Parliament, Council
2017	MDR published on May 5, 2017
2020	End of three-year transition on May 26, 2020



Medical Device Regulation

Devices falling in the scope of the MDR
Compliance from:
26 May 2020

Current Notification of NBs
Void:
26 May 2020

Relevant conditions to place devices on the EU market

From 26th May 2020 no significant changes in design & intended purpose

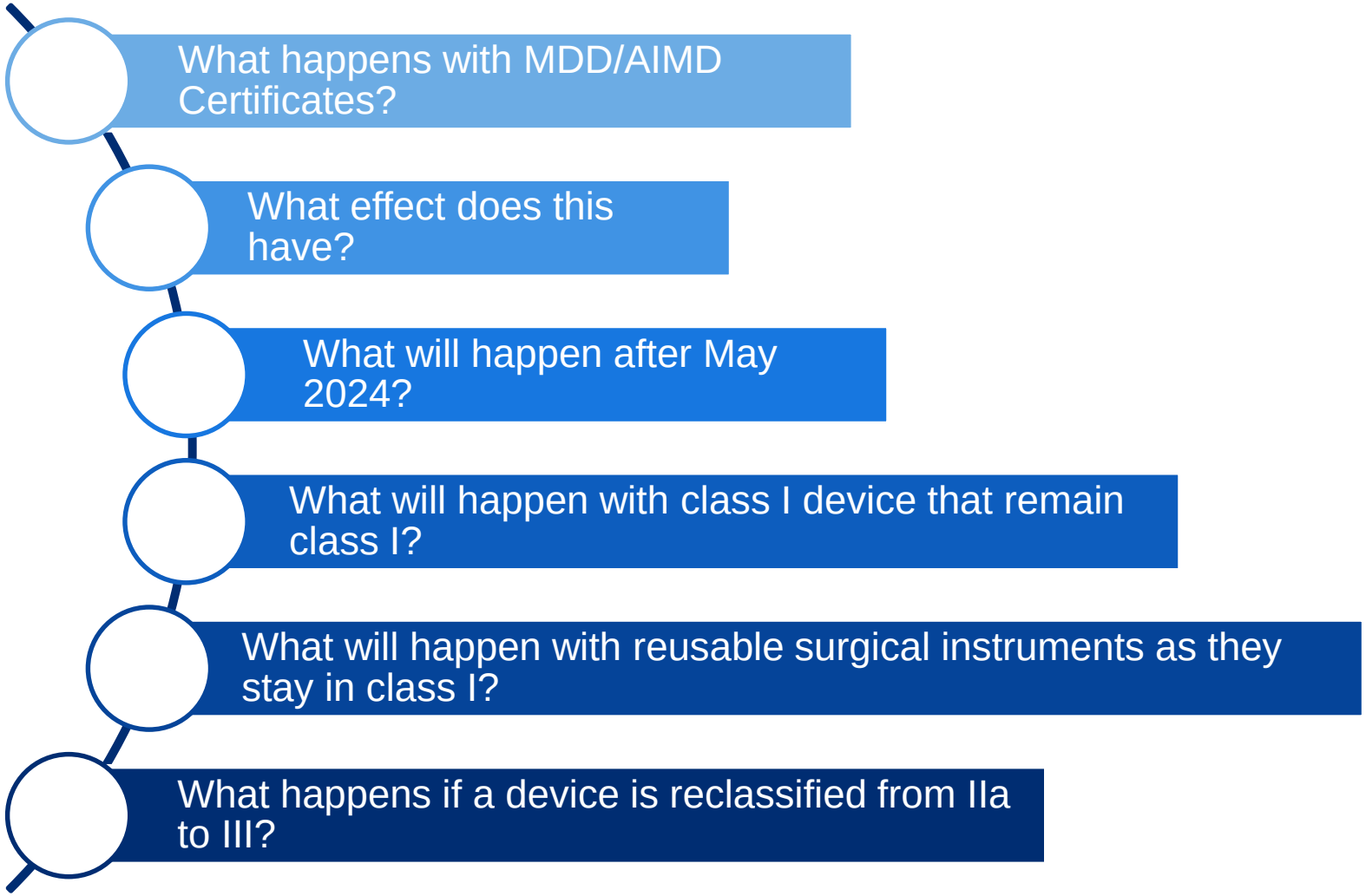
Post-market surveillance requirements of the MDR must be fulfilled

From May 26th 2020 reporting of SAE & device deficiencies per MDR

Registrations of Economic Operators & devices per MDR

Made available or put into service until 27th May 2025

Some rules for the grace period 2020 – 2024



Challenges for Manufacturers

- Competence must be built
- QMS must be adapted
- Manufacturers must adjust TD and agree it with NB
- Up-classifications to be considered (e.g. spinal devices)
- Consultation procedures to be considered
- Check the clinical data – is it sufficient?
- Higher requirements on PMS – Resources available?

Do not forget the main aim of regulations

…be realistic in setting expectations

The European Medical Device Approval is getting tougher than the US FDA System

Innovation starts to go first to the US instead of coming to Europe

Does this fulfil the main aim of the European regulation towards a better healthcare system in the EU?

Do not forget the main aim of regulations

…be realistic in setting expectations

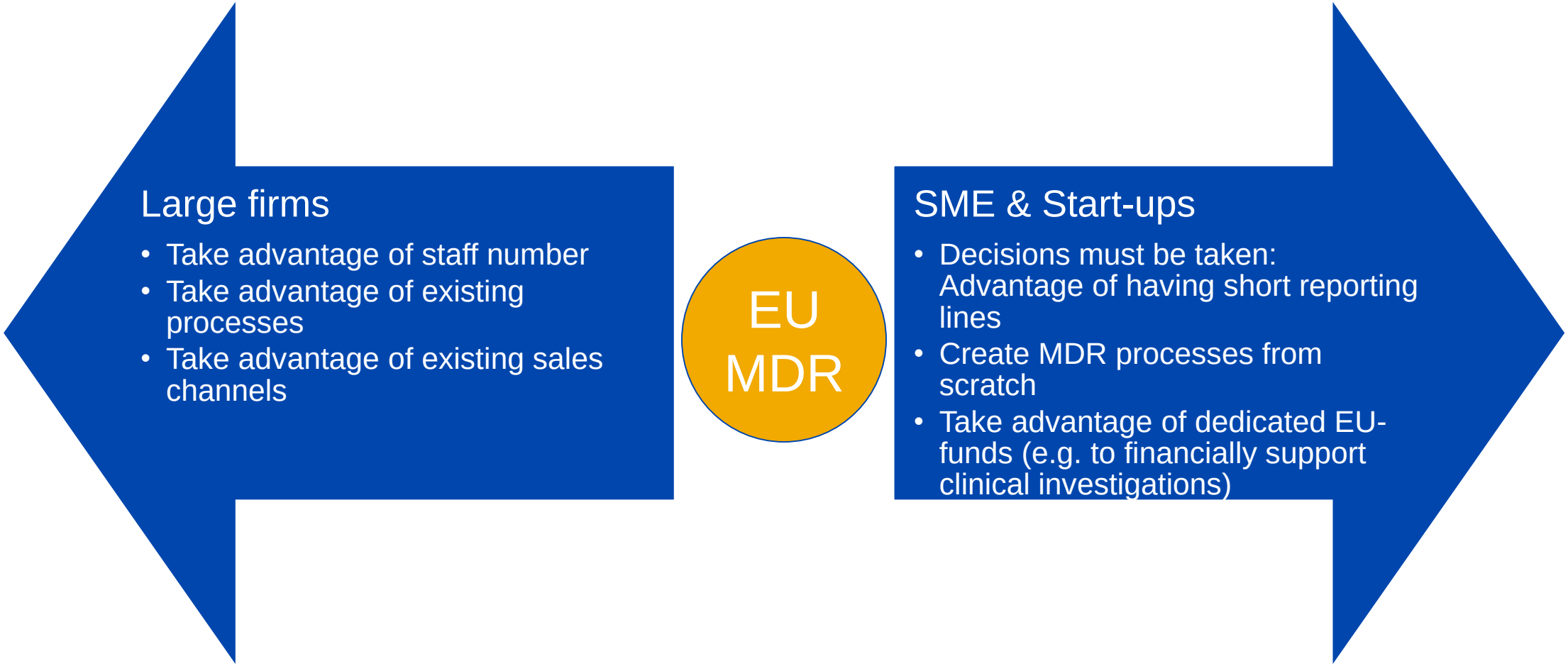
Patient benefit and safety expectations should be in focus

Continuity of state of the art healthcare system must be ensured

Innovation towards a better healthcare system must be supported

Formalistic expectations must be eliminated

Chances for big and small manufacturers



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