



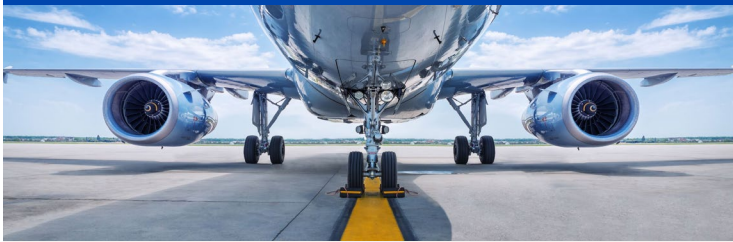
# Structured Dialogue @ TÜV SÜD





**Add value.  
Inspire trust.**

# Structured dialogue: Possible topics of interest







## Application & Onboarding



-  Onboarding process
-  Application forms & review process
-  Sites, suppliers & devices
-  Device classification & code assignment




## Topics of manufacturer



-  TÜV SÜD Testing & Certification Regulations
-  MDR/IVDR Framework Agreement
-  Handling of device and other changes
-  Transfer to TÜV SÜD Notified Body

## Conformity Assessment Procedure



-  Project planning, time limits special procedures (e.g. consultation)
-  Submission requirements
-  Costs, fees & other financial aspects
-  CS, guidance documents & harmonized standards

# Always wondered how to address these topics with your Notified Body?

Planning meetings for your MDR/IVDR product according to your needs and availabilities

Applicable assessment modules

Potential project plan including all required documentation

How to make best regulatory plans when planning new technologies or business lines



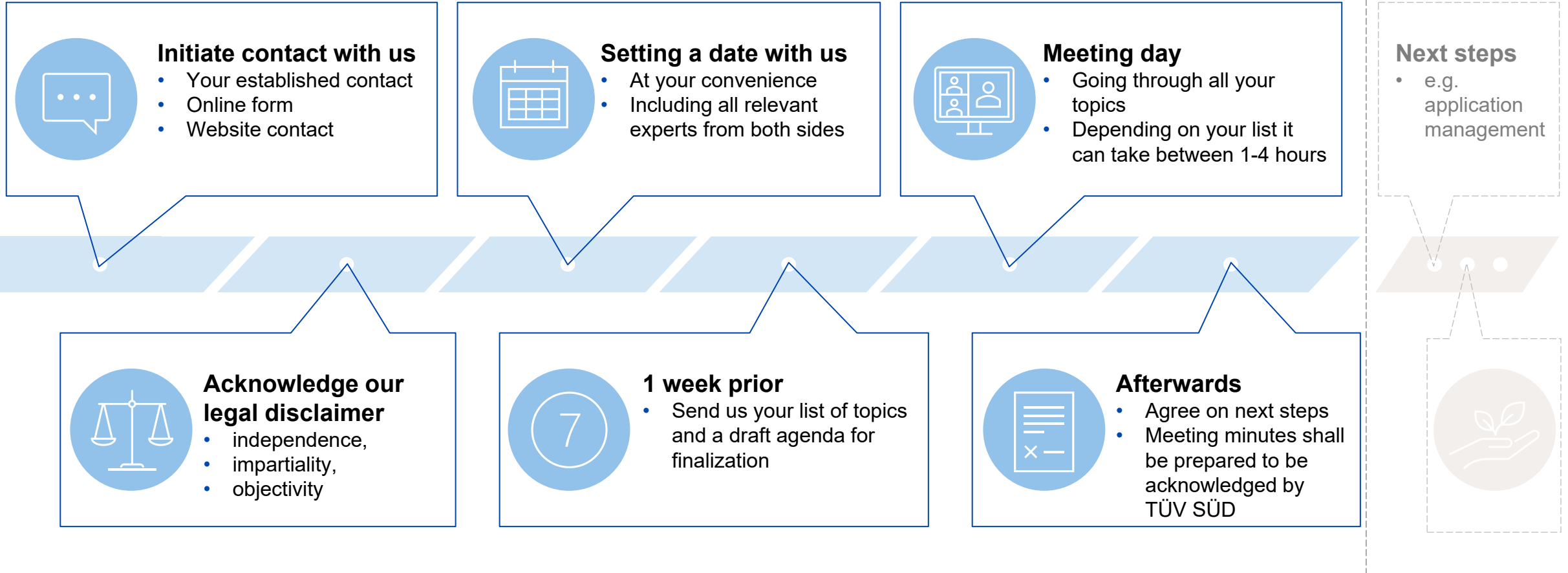
I would like to know more about procedures and timelines when working with TÜV SÜD.

Can I have a technical meeting to discuss the submission strategy when considering a product change?

What do I need to know when considering changing my Notified Body?

# How to organize a structured dialogue with us @ TÜV SÜD

1.5 - 6 weeks





As a notified body,  
**TÜV SÜD is**

- 👉 Independent
- 👉 Objective
- 👉 Impartial



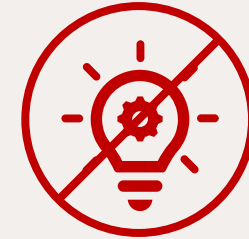
## General training activities

- not client specific
- relate to regulation of devices or related standards



## Technical meetings

- for the purpose of the exchange of technical information and regulatory guidance



**Our services do not include pre-certification or consultancy services** that may imply providing client- or product-specific solutions



Examples:

- × *gap analysis,*
- × *check of MDR/IVDR readiness,*
- × *mock-files instead of complete TD assessment,*
- × *technical solutions,*
- × *individual questions about system/product design*



# Thank you



**Reach out to us if you have any questions:**

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