SGS

Speaker

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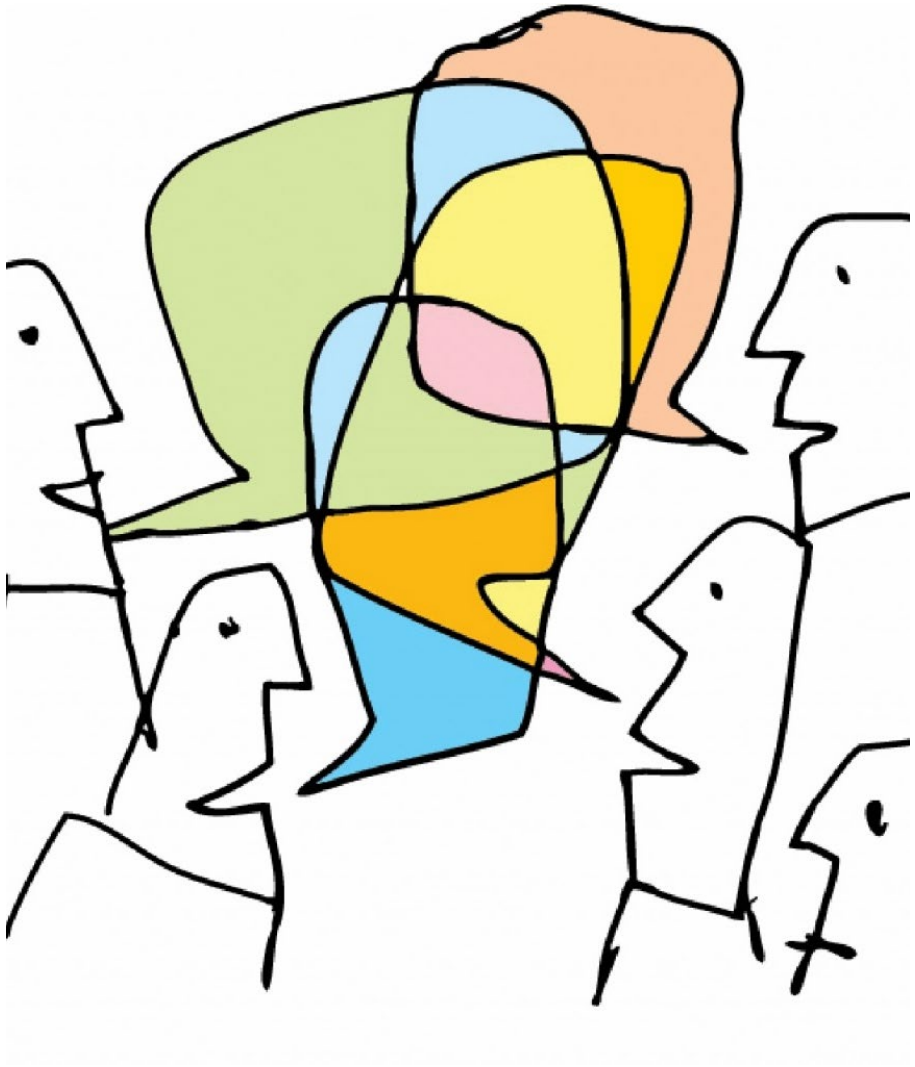
- EU Schemes (MDD, MDR, UKCA)
- Active devices + MDSW
- MSc Mechanical Engineer (BUTE, Hungary)
- Industry career as design engineer (automotive, medical X-ray)
- 17+ years NB, MDSAP AO exp.



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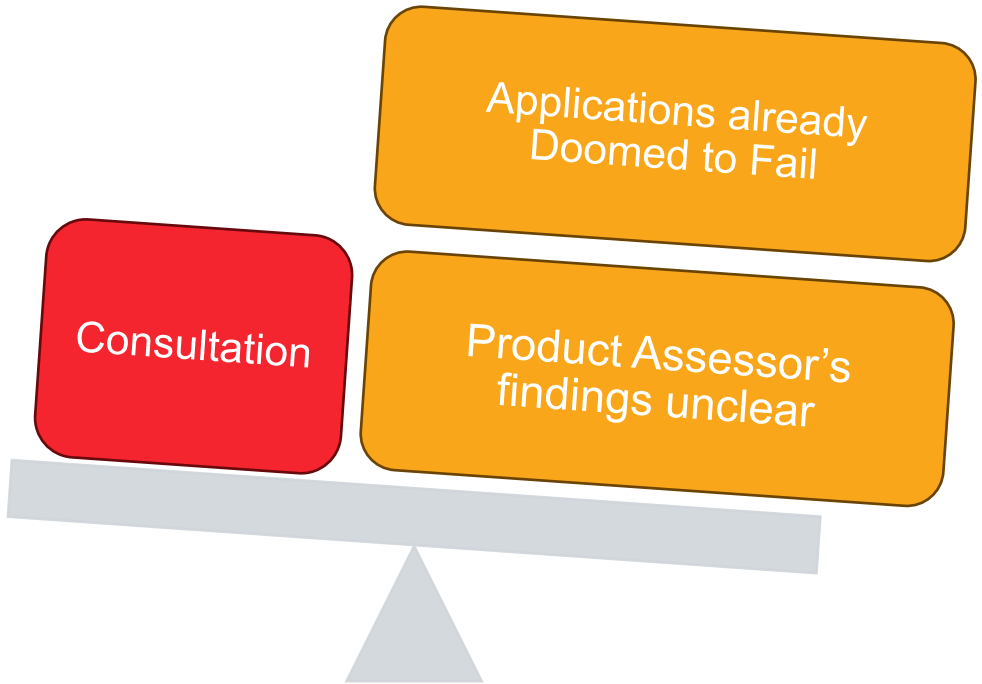
Regulatory basis – step 1

- In accordance with Section 1.2.9. of Annex VII to the MDR, the independence and impartiality requirements laid down in Section 1.2. “in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment”

Threat to impartiality



Excessively burdensome conformity assessment

Regulatory basis – step 2

(based on the MDR text):

MDCG 2022-14 (Notified body capacity and availability of medical devices and IVDs):

15. The MDCG encourages notified bodies and manufacturers to organise **structured dialogues** before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body. **Such dialogues should not be considered consultancy service**. [actors: MDCG, NBO]

Regulatory basis – step 3

(based on the MDR text and MDCG guidance):

Team NB – **Code of Conduct** version 5, 2024-09-16

The European Association
Medical Devices - Notified Bodies

NBs can discuss (non-exhaustive examples):

- Project plans
- Submission requirements
- Requirements for reporting change
- Use of guidance, standards and common specifications
- Costs and timelines

NBs cannot (non-exhaustive examples):

- Complete gap analyses
- Check for MDR/IVDR readiness (a.k.a. pre-audit)
- Review mock files for MDR/IVDR conformity
- Review clinical development strategy
- Provide technical solutions
- Explain how the manufacturer should meet specific regulatory requirements

Or not...

„There may not be a need for Structured Dialogue if information is provided in Best Practice Guidance Documents.”

SGS Structured Dialog approach – as of 2025 Jan

Before/during MDR/IVDR application, SGS **can** help with:

- Filling SGS specific forms, explaining the expected content of certain fields
- Check for plausability of application (is it MD, classification, common use of terminology, etc)
- Providing general pointers to the level of Product (TD) + QMS readiness expected by the NB to ensure smooth conformity assessment
- Providing feedback that the applicant would benefit from the use of consultant(s) and/or external training, and provide a list of trustworthy 3rd party consultants and training providers

SGS Structured Dialog approach – as of 2025 Jan

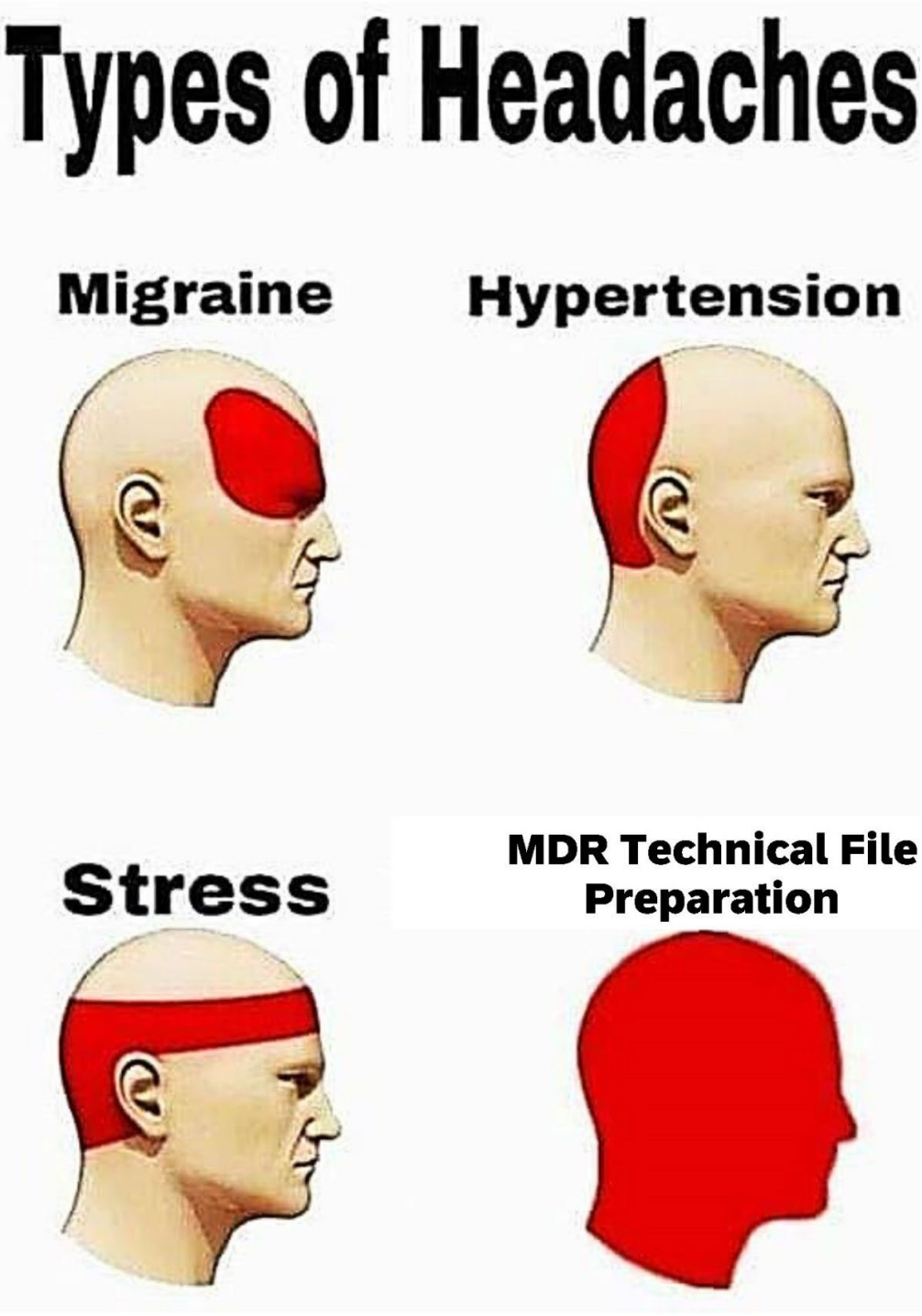
Before/during MDR/IVDR application, SGS **can** help with:

- Pointing out pros and cons of various conformity assessment related regulatory strategies (e.g. device vs procedure pack, including some or all products in the initial MDR CAP)
- SGS / MDR / IVDR conformity assessment specific information not otherwise used by the manufacturer, like:
  - device subcategory (e.g. MDA/MDN codes),
  - applicable technology codes (MDS/MDT codes),
  - confirming most appropriate EMDN code for Class IIb devices
  - definitions for relevant suppliers and subcontractors,
  - etc.

SGS Structured Dialog approach – as of 2025 Jan

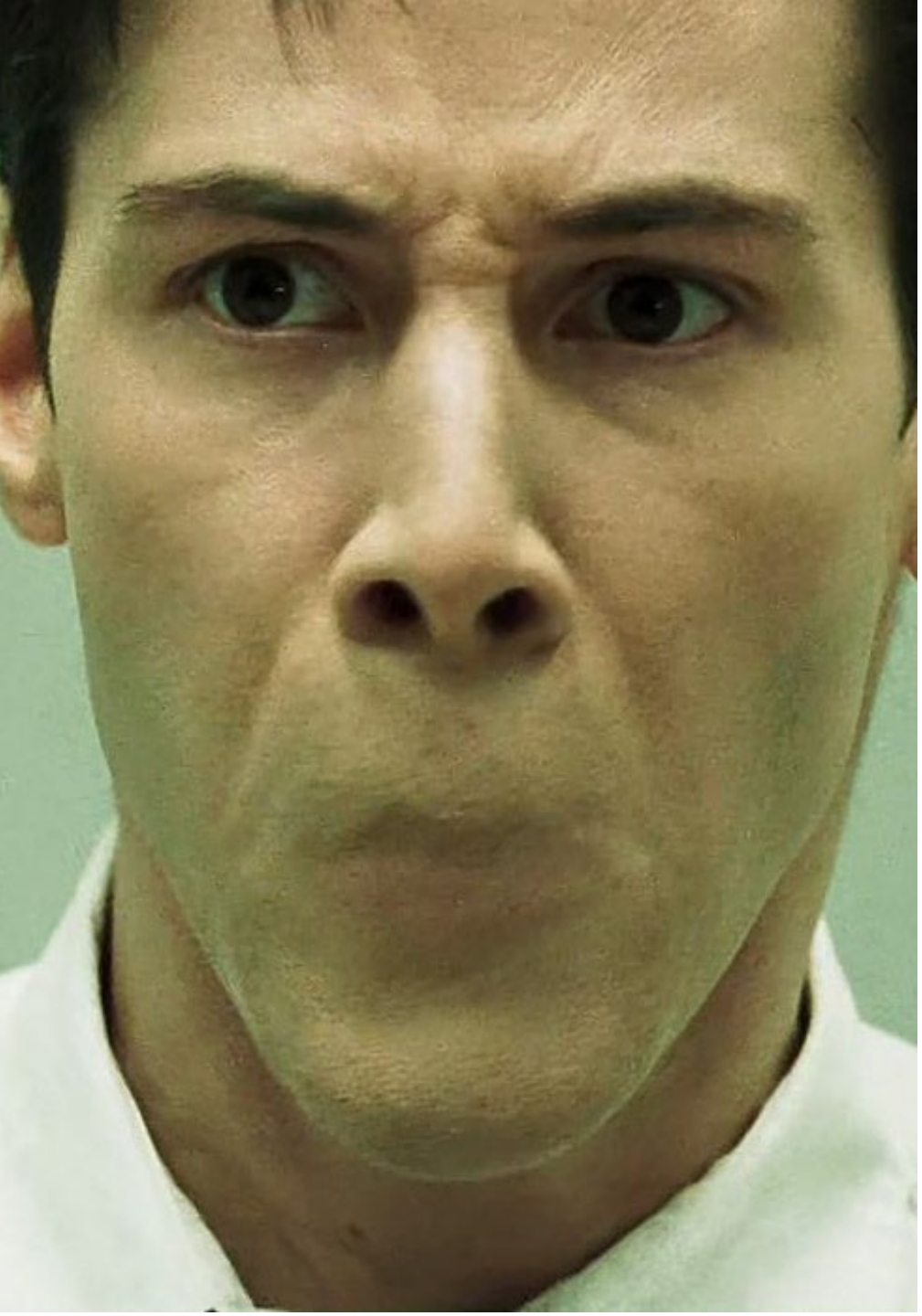
Before/during MDR/IVDR application, SGS **will not** help with e.g.:

- Doing the manufacturer's homework, e.g.:
  - Decide on classification rule and resulting class
  - UDI structure
  - Creating application attachments (e.g. Flowchart, org-charts, etc)
- Finding the manufacturer's supply chain, e.g. EC-REP, CRO, etc.



During the MDR/IVDR conformity assessment, SGS can help with:

- Explaining the applicability of standards and guidelines
- Explaining why something is a nonconformity following and audit or TD review round
- Explaining the applicable quality and regulatory requirement(s)
- Reviewing a draft change notification to see if it is potentially significant



During the MDR/IVDR conformity assessment, SGS won't help with:

- Brainstorming how the manufacturer can/should meet certain requirements, including examples from other clients
- Dictate or suggest how the manufacturer should change their documentation to address already established findings

2025 and beyond; what's next?

- NBs collect data and continue internal discussions about the boundaries and practical applciation of Structured Dialogue so that it
  - Helps manufacturers avoid known common pitfalls
  - Reduces the threat to impartiality

- SGS in particular is in the work of publishing a structured dialogue guideline in Q1 2025

Thank you!

Do you have any questions?

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https://www.sgs.com/en/our-services/business-assurance/medical-devices-regulatory-compliance

When you need to be sure