



Structured dialogue with SGS Fimko

What is Structured Dialogue?

MDCG 2022-14 and MDCG 2019-6 rev. 5 encourage Notified Bodies and manufacturers to organize structured dialogues. Structured dialogue is a formalized process of communication between a Notified Body and a manufacturer prior to, during, and after the conformity assessment process.

Its goal is to clarify expectations, ensure completeness of submissions, and improve efficiency without crossing into consultation. Structured dialogue helps to identify gaps early and fosters mutual understanding, while maintaining the Notified Body's impartiality.

The focus of the structured dialogue should be on what needs to be fulfilled, not how to fulfill it. Manufacturer's questions should respect the Notified Body's independence, objectivity and impartiality requirements and should not lead to consultancy.

The responsibility to meet the regulatory requirements remains with the manufacturer. Structured dialogue is not a formal conformity assessment and does not replace any official review nor affect any future certification decisions.



What is allowed?

- Generic questions about the certification process (e.g., timelines, steps, submission requirements)
- Administrative questions (scheduling, project plans, channels)
- Questions requesting feedback on proposed approach, e.g.,
 - Does our understanding of the Clause X requirements appear sufficient?
 - We plan to use the route X. Are there any concerns with this approach?

What is not allowed?

- Asking advice regarding the design, construction, marketing or maintenance of devices or processes,
- Asking questions regarding how to comply
- Questions requesting solutions or instructions
 - What test should we use?
 - What evidence is needed for this GSPR?
 - What clinical evidence is required for this device?

Structured Dialogue topic examples

Pre-application

- Principles of classification
- Application process
- Conformity assessment process
- Transfer from another NB to SGS Fimko
- Client onboarding
- Pricing and fees
- Timelines

Application

- Clarification on the data /documentation to be provided with the application
- Certification process
- Contract management
- Change management

Conformity assessment

- Discussion on a planned significant / substantial change and the consequences on certification process
- Sufficiency of quality /quantity of clinical data
- Leveraging previous assessments
- Clarification of raised non-conformities and missing data
- Appropriateness of PMCF/ PMPF plan

Post-Certification

- Technical and regulatory questions
- Change management
- Certificate maintenance
- Surveillance activities
- Re-certification

Before the application is submitted, the Notified Body cannot perform any activities that could fall under the definition of conformity assessment, such as reviewing clinical/performance data or assessing the QMS. This also includes activities like gap analyses or MDR/IVDR readiness checks, which would be considered consultancy.

Our Structured Dialogue Process

1 Request a Structured Dialogue with SGS Fimko

- If you are a new client, please contact us via this [contact form](#) or by email, and our expert will get back to you.
- If you want to initiate structured dialogue and you are an existing client, please contact your designated contact person at SGS Fimko, who will assist you further.

2 Submit your questions and materials to SGS Fimko

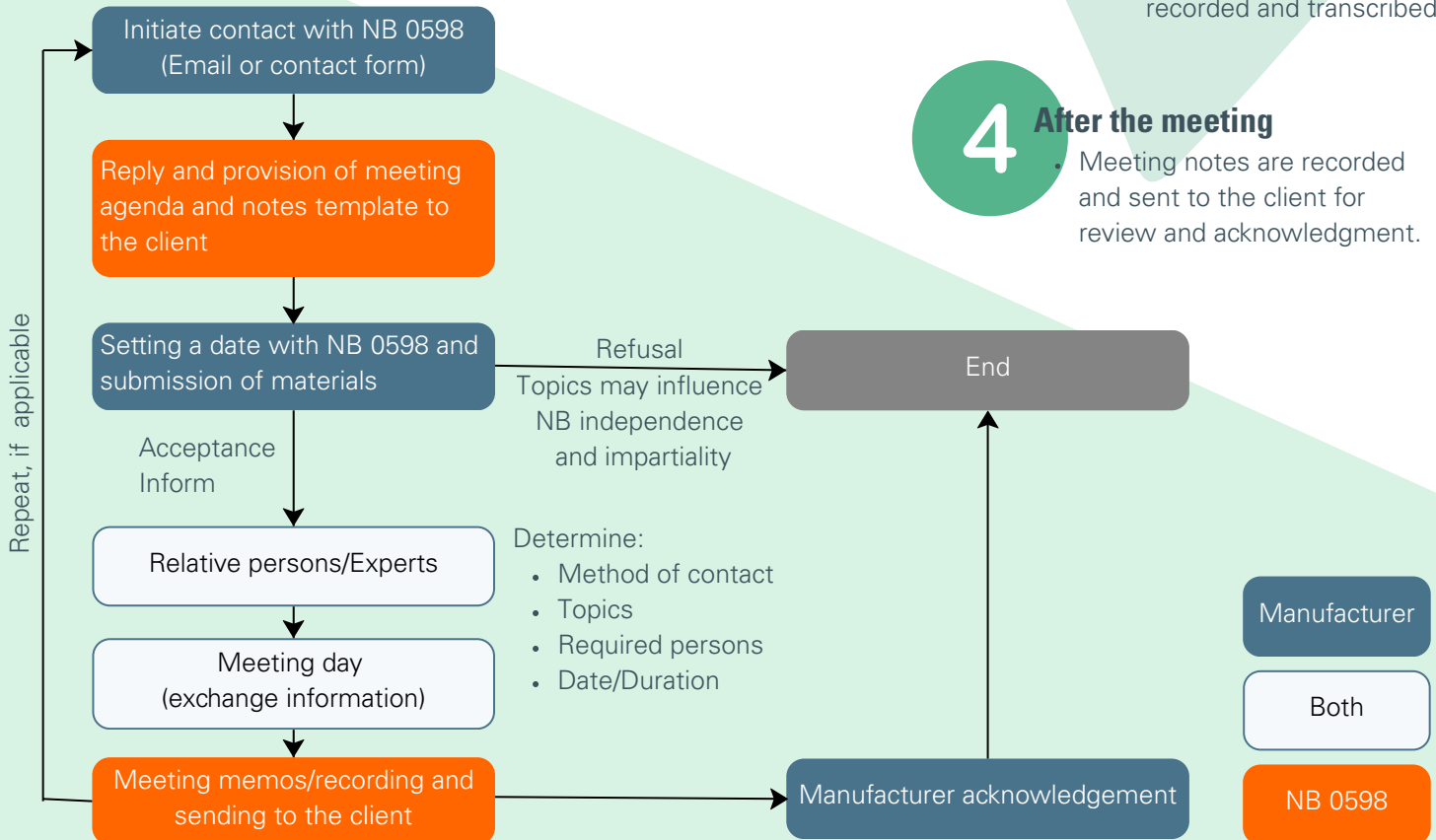
- Submit the materials well in advance to ensure that SGS Fimko is able to bring in the relevant experts to the meeting.
- This also allows SGS Fimko to check the requested topics/questions are acceptable.

3 Structured Dialogue meeting

- Duration of the Structured Dialogue is 0.5 – 1 hrs depending on the topics.
- Video and audio recording of the meeting are not allowed.
- Meeting notes will be recorded and transcribed.

4 After the meeting

- Meeting notes are recorded and sent to the client for review and acknowledgment.



When you need **to be sure.**
sgs.com

Contact us:

IVD devices:



IVD.Devices.Fimko@sgs.com

Medical devices:



NBMed.Fimko@sgs.com

Follow us:



[linkedin.com/company/sgs/](https://www.linkedin.com/company/sgs/)

SGS

When you need to be sure